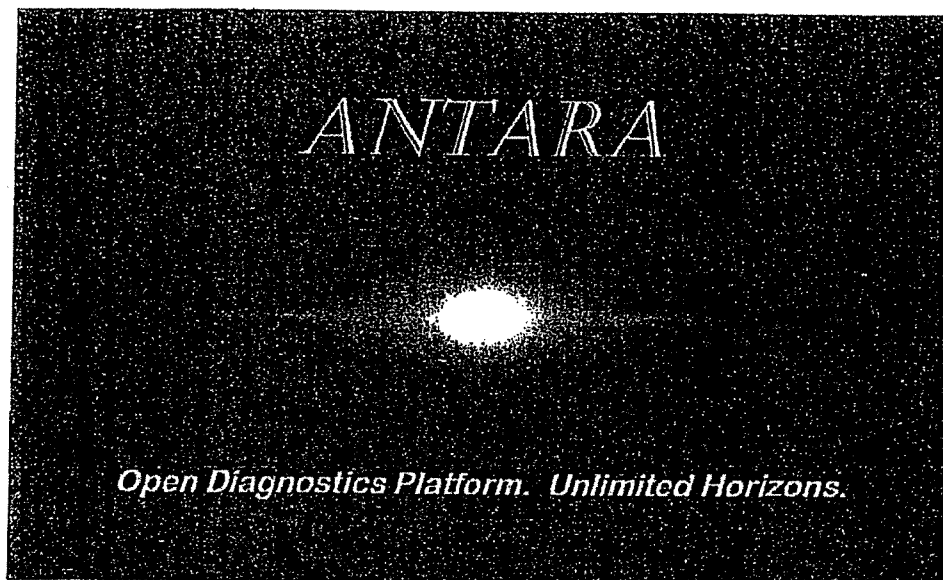




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Electrochemical DNA Chip Based Diagnostic Technologies  
Powered By:

**Toshiba**

**CONFIDENTIAL  
BUSINESS PLAN**

February 15, 2006

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**Antara Bioscience Inc.**  
**Business Summary**

Antara, a U.S. Delaware Corporation, has a startup valuation of \$10 million US dollars (Paid-In-Capital) through the founders of the company. Antara's primary business is to license, further develop, and sell the Toshiba Genelyzer™, Toshiba chips, and related services made available to Antara through an exclusive license spanning no less than 15 years. In addition to the license, Toshiba will provide Antara with the knowledge and information necessary to:

- (1) prepare the product for market introduction
- (2) establish the product as a worthy competitor in the in-vitro diagnostic market,  
and
- (3) to prepare the product for FDA approval.

**Goals**

An Initial Public Offering (IPO) in 12-18 months is our goal. To achieve this we have inquired with investment houses (such as J.P. Morgan) to provide a rough analysis of possible market capitalization. Here are two possible scenarios:

**Scenario 1:- Cash Balance of \$50 Million - \$75 Million US Dollars**

- Some Intellectual Property

→ Valuation at IPO of \$350Million to \$500Million US Dollars

**Scenario 2:- Cash Balance of \$50 Million - \$75 Million US Dollars**

- Some Intellectual Property
- At least one license agreement or a Homeland Security Contract valued at \$50Million US Dollars

→ Valuation at IPO of \$750Million to \$1Billion US Dollars

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**Initial/Round 1 Financing**

Our initial/round 1 financing "goal" is to raise \$75Million US dollars by March 31, 2006. The terms and options for this round of financing are:

Issue Price: 20,000JPY per share

Offer Dates: Between March 1 and March 15, 2006

Investment Dates: Between March 16 and March 31, 2006

Antara Bank Info: Please wire funds in Yen to:

Bank of Tokyo-Mitsubishi Tokyo  
FAO Bank of Hawaii, Honolulu  
A/C 653-0409596  
FFC Antara Biosciences Inc.  
Attn: Treasury #244

→ Special Provision: If funds are invested before February 28, 2006, the issue price will be 10,000 JPY per share.

**Plus options in Antara Japan.**

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### Proposed Time lne of Money expenditure

10 oku yen for Deposit to Toshiba, plus 75 oku yen for operations.

February 28<sup>th</sup> = Yen 10 oku

March 30<sup>th</sup> = Yen 30 oku

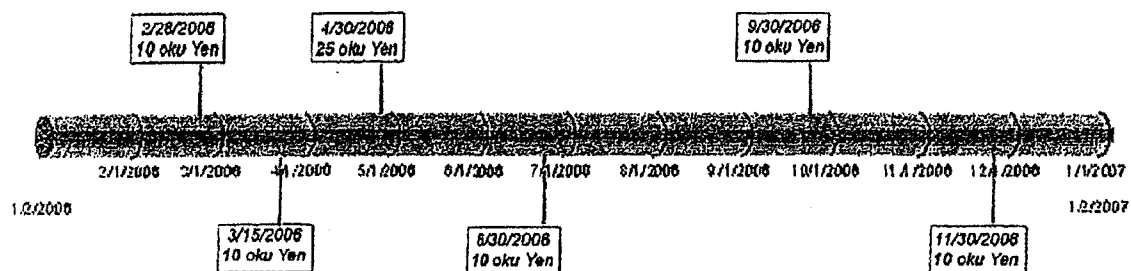
June 1<sup>st</sup> = Yen 15 oku

August 1<sup>st</sup> = Yen 10 oku

September 30<sup>th</sup> = Yen 10 oku

November 30<sup>th</sup> = Yen 10 oku

### *Antara Proposed Financial Milestones (2006)*



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**Five-Year Projections**

In the first 30 – 90 days we will need \$40,000,000 to make the initial payment to Toshiba and also to secure the facility, equip the lab, hire key staff, and start business operations.

The five-year projections reflect the cost projections to include the FDA approval process, as well as revenue projections.

**Autara**  
**PROJECTED FIVE YEAR EXPENSES**

**Expense Projections**

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEARS 5
Description	Cost	Cost	Cost	Cost	Cost
FDA Approval Process	\$ 10,000,000.00	\$ 10,000,000.00	\$ 30,000,000.00	\$ 30,000,000.00	\$ 25,000,000.00
Operating Cost					
Infrastructure					
Equipment	\$ 2,000,000.00	\$ -	\$ -	\$ -	\$ -
Office (remodel, furnish, equip)	\$ 1,500,000.00	\$ -	\$ -	\$ -	\$ -
Facility	\$ -	\$ 8,500,000.00	\$ 18,500,000.00	\$ -	\$ -
Salaries/Lease	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00
Research and Development	\$ 15,000,000.00	\$ 20,000,000.00	\$ 25,000,000.00	\$ 25,000,000.00	\$ 25,000,000.00
Intellectual Property					
Patent Prosecution/Opinion	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00
In-Licensing	\$ 2,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00
Litigation Reserves	\$ -	\$ 5,000,000.00	\$ 10,000,000.00	\$ 10,000,000.00	\$ 10,000,000.00
Marketing and Advertising	\$ 2,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 10,000,000.00
Salaries	\$ 7,500,000.00	\$ 9,000,000.00	\$ 10,000,000.00	\$ 11,000,000.00	\$ 15,000,000.00
General Administrative	\$ 2,000,000.00	\$ 2,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00
Information Technology (IT)	\$ 1,500,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00
Legal	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00
Regulatory	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00
Consultants	\$ 4,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00

Subtotal: \$ 54,000,000.00 \$ 76,000,000.00 \$ 119,000,000.00 \$ 132,500,000.00 \$ 141,500,000.00

TOSHIBA Initial Payment JPY 1,000,000,000  
 Clinical Laboratory for ASR \$ 10,000,000.00 \$ 15,000,000.00 \$ 25,000,000.00 \$ 30,000,000.00 \$ 35,000,000.00

**TOTALS** \$ 74,000,000.00 \$ 91,000,000.00 \$ 144,000,000.00 \$ 162,500,000.00 \$ 176,500,000.00

Revenue Projections					
Markers (Hepatitis, Liver, Rheumatoid, Colon, etc.)	\$ -	\$ 30,000,000.00	\$ 60,000,000.00	\$ 180,000,000.00	\$ 180,000,000.00
Infectious Diseases	\$ 20,000,000.00	\$ 50,000,000.00	\$ 100,000,000.00	\$ 250,000,000.00	\$ 250,000,000.00
- bird flu detection					
- mad cow detection					
Human Lung Security	\$ 50,000,000.00	\$ 75,000,000.00	\$ 75,000,000.00	\$ 100,000,000.00	\$ 100,000,000.00
- Antirabies					
<b>TOTALS</b>	\$ -	\$ 70,000,000.00	\$ 155,000,000.00	\$ 235,000,000.00	\$ 500,000,000.00

**Profit** \$ (74,000,000.00) \$ (71,000,000.00) \$ 11,000,000.00 \$ 102,500,000.00 \$ 358,500,000.00

**New Fund Money** \$ 75,000,000.00 \$ 25,000,000.00 \$ - \$ - \$ -

**Financial Balance** \$ 1,000,000.00 \$ 5,000,000.00 \$ 16,000,000.00 \$ 118,500,000.00 \$ 477,000,000.00

Human Resource					
Manpower	15	20	25	25	25
Staff and equipment	20	50	75	100	120

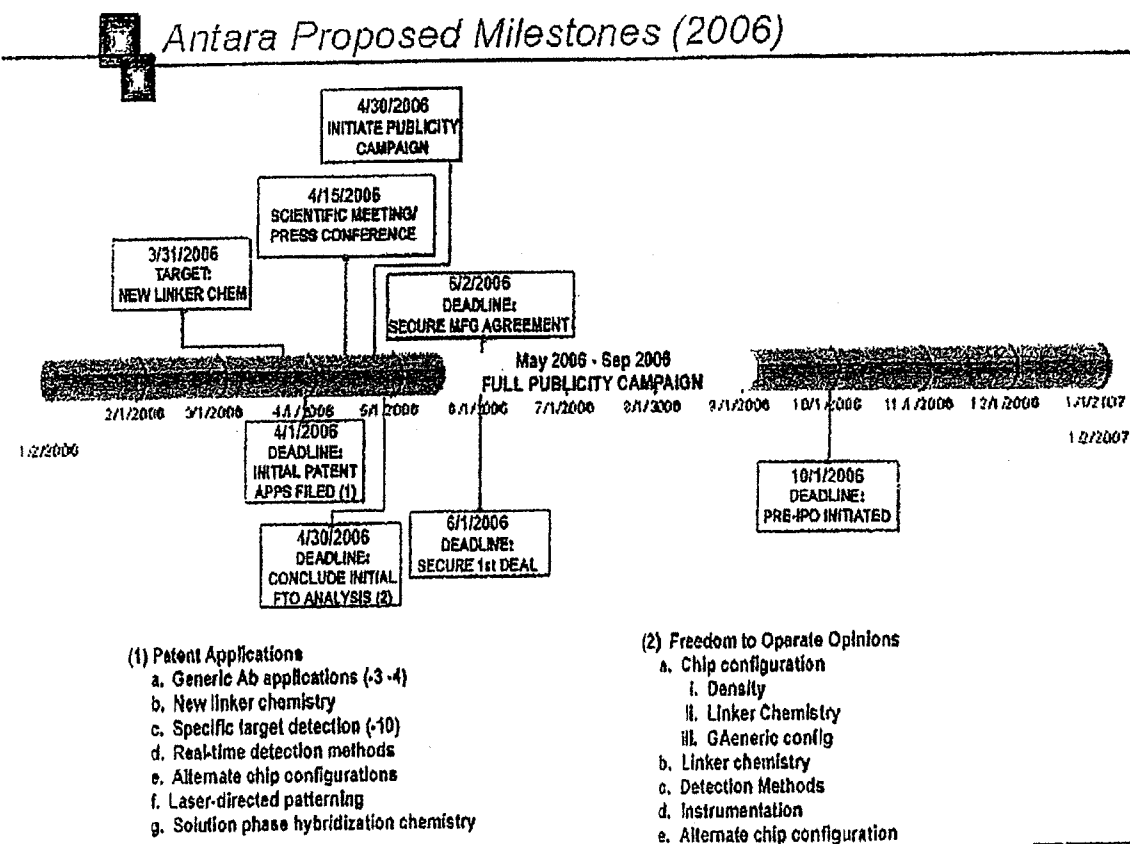
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## Timeline

Antara has successfully negotiated a Patent License Agreement with Toshiba which should be through the Ringi process by February 10, 2006.

Antara is moving forward with the setup of their headquarters in Mountain View, California. The site is a two-story building with 44,000 square feet (4088 m<sup>2</sup> / 1237 tsubo) of prime laboratory and office space.

We are proposing an aggressive timeline to take advantage of market and investment opportunities. The 2006 timeline forecast is reflected below.



Antara is committed to the success of this business and with Toshiba's commitment and finalization of the Exclusive Patent License Agreement, we are well on our way.

A detailed business plan follows.

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## 1. Executive Summary

ANTARA BioSciences, Incorporated ("ANTARA" or "the Company") is focused on the development, manufacture and sale of electrochemical chip-based *in vitro* diagnostic (IVD) systems and services that are expected to revolutionize *in vitro* detection. ANTARA brings to market a proprietary diagnostics platform, which replaces traditional detection methods with a pioneering combination of standard molecular biological techniques and electronic detection. Invented by Toshiba Corporation, the Genelyzer™ chip platform enables rapid (as little as 10 minutes for some applications) *in vitro* diagnostic evaluation. This platform offers greater sensitivity than existing technologies; in some instances, several orders of magnitude more sensitive than existing technologies.

The markets for the Company's products currently include all sectors of the IVD market, molecular biology research in the life sciences, basic human disease research, genetic analysis, pharmaceutical drug discovery and development, pharmacogenomics (research relating to how a person's genes affect the body's response to drug treatments – often called personalized medicine), toxicogenomics (research relating to the measurement of gene expression as a predictor of toxicity) and clinical diagnostics. Additional markets are expected to emerge in such fields as agricultural research, plant breeding, food testing, pathogen identification and consumer pharmacogenomics and diagnostics.

Under the leadership of an experienced and diverse management team, ANTARA's basic business strategy includes establishing a market-leading position, by providing the first viable alternative to nucleic acid amplification-based techniques (e.g. PCR) and traditional signal-based diagnostics (e.g., fluorescence). Our combination of proprietary technologies and proven expertise enables the rapid detection of critical disease markers and will facilitate discoveries across many disciplines. The clinical applications of the Company's technologies for diagnosing and treating disease is an emerging market opportunity in health management that provides an unprecedented opportunity to improve the effectiveness of healthcare by collecting information about DNA variation (e.g., single nucleotide polymorphisms "SNP") and gene expression in patients at various times from prognosis, through diagnosis and throughout therapeutic delivery and monitoring.





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### 1.1. Company Objectives

*In vitro* diagnostics, including molecular diagnostics, continue to be an increasingly competitive, yet profitable business sector. *In vitro* diagnostic products have become an integral component of accurate disease identification, prevention, management, and treatment, with their use increasing in dramatic fashion. *In vitro* diagnostics have proven their value by transforming the health-care industry through the improvement of testing standards and by increasing the speed in which highly accurate results are obtained. Advancements in molecular biology and development of techniques such as nucleic acid sequencing, nucleic acid amplification, single nucleotide polymorphism (SNP) detection, *in situ* hybridization/detection and nucleic acid arrays, have significantly advanced the field of *in vitro* diagnostics (IVD).

The world-wide revenues for IVD products and services exceeded \$28 billion (\$28B) in 2004 and are expected to continue a positive growth trajectory over the foreseeable future with estimated world-wide revenue approaching, if not exceeding, \$50B by 2010. The molecular diagnostics market segment is currently the fastest growing segment of the overall IVD market – exhibiting a current growth rate in excess of 15% per year. However, considerable barriers to entry have existed due to technical limitations, ineffective sensitivity and aggressive enforcement of patents and other intellectual property. The cumulative effect of these factors is a constant demand for alternative emerging technologies.

ANTARA seeks to meet or exceed the current detection standards in the relevant markets/fields and achieve significant market penetration within a 12 to 24 month period.

### 1.2. Mission

To establish a dominant IVD platform based upon the pioneering technology developed by Toshiba Corporation, coupled with the combined expertise of the Company's principle partners and an expert leadership team. Our products and services are based upon novel, proprietary, and proven technology that provides an open diagnostic platform that can be applied to virtually any IVD application. The Company seeks to achieve rapid market penetration and secure a dominant market share of the ever-expanding global *in vitro* diagnostics market. ANTRA will deliver the first viable alternative to traditional methodologies and provide a level of sensitivity that meets, and in most cases exceeds, presently available technologies and standards.



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## 2. Company Summary

The Company draws upon the diverse expertise of its founding partners. At its core, proprietary electrochemical DNA chip technology, originally designed and implemented by Toshiba Corporation. The researchers responsible for this pioneering invention have joined the Company and are complemented by state-of-the-art research facilities, world-class research talent, a high-throughput FDA registered (CLIA) clinical laboratory and a Management Team composed of proven industry leaders. This combined expertise provides unparalleled synergy, which holds the potential to revolutionize *in vitro* diagnostics.

### 2.1. Founding Corporate Partners

#### 2.1.1. Toshiba Corporation

##### TOSHIBA

Toshiba Corporation marked its 130th anniversary in 2005. Toshiba is one of the world's largest companies -- a global leader in the fields of electronics with undisputed excellence in the areas of semiconductors, notebook PCs and digital consumer products. Toshiba's expertise in these areas has enabled truly breakthrough technology.

Toshiba has emerged as an important contributor to the advancement of *in vitro* diagnostics with the development of the most advanced electrochemical chip design and state of the art electronics/instrumentation. Seeking to apply its expertise in electronic instrumentation and semiconductor fabrication, a project was launched to replace radiation and optically based (e.g., fluorescence) detection with the goal of eliminating the need for pre-detection amplification. Recognizing that all known methodologies rely upon a signaling event that had to be distinguishable from background noise and interference, Toshiba embarked upon a project to directly detect the electrochemical event that occurs upon DNA hybridization, and then amplify that electrical signal, obviating the need to amplify the target molecule. Unlike radiation or fluorescence methods, the electrochemical detection allows for selective amplification of the desired signal, doing so in a manner analogous to amplifying a radio signal. The result, Toshiba's Genelyzer™ chip and instrument, has achieved detection sensitivity beyond traditional techniques, with proven success in two of the most challenging areas of diagnostics - pharmacogenomics and SNP typing.

Toshiba announced its first electrochemical DNA chip in October 2001. The original device employed a computer-interfaced chip and was used to support the development of individual interferon treatment regimes for patients infected with hepatitis C. The company continued its R&D, expanding its with a team from the Graduate School of Pharmaceutical Sciences of Osaka University, led by Professor Junichi Azuma, of a chip that probes treatment efficacy and side effects for individual patients in six areas of illness: tuberculosis, digestive disorders, ademonia, hyperlipemia, cardiac arrest and cancer.

The current configuration has a demonstrated a sensitivity of 1 copy/μl, 1-3 orders of magnitude more sensitive than currently available systems. Ongoing development efforts include the creation of a CMOS chip which integrates the amplifier and the substrate,

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increasing detection sensitivities by as much as 3-5 orders of magnitude - a theoretical detection limit of 10 copies/pl, making it the most sensitive detection system to date.

#### 2.1.2. Eurus Japan (Eurus Genomics, Inc.)

株式会社 ユーラス & Eurus Genomics Inc.  
Eurus Japan Ltd. & Eurus Genomics Inc.

Eurus - Japan is a Japanese company located in Tokyo, Japan with a wholly owed US subsidiary, Eurus Genomics, Inc., located in Honolulu, Hawaii. Eurus strives to build strategic alliances with partners representing many facets of the corporate environment equating to an international force of experienced individuals attune to customs and culture, yet capable of providing a multitude of specialized services. Eurus has implemented a novel international business model that enables the development, implementation, and commercialization of biomedical technologies.

Eurus has established keystone partnerships with the Japan National Cancer Center (the "JNCC"), the National Cancer Institute in Maryland, ("NCI") the State of Hawaii (the "State"), the University of Hawaii John A. Burns School of Medicine (the "Medical School"), and Clinical Laboratories of Hawaii, LLP (the "CLH"). Our legal advisors, Patton Boggs LLP (Patton Boggs), provide legal advice and assistance in securing patent protection, regulatory approval (including FDA approval) and government relations representation. Eurus's largest client is a consortium of leading Japanese pharmaceutical companies (collectively, the "Consortium").

Eurus' foundational business goals include (1) identification and discovery of new medical discoveries through the integration of pharmacogenomics, which will lead to new drug development and marketing. Pharmacogenomics is the combination of pharmacology and genomics to study and understand how a person's genetic makeup affects the body's response to a drug, and (2) assisting emerging biotechnology efforts by providing intellectual collaborative technical assistance and patent consultation in order to successfully introduce new discoveries to the USA, Japan, and European markets in the most expeditious and effective manner.

Eurus has assembled a team of researchers having peer-recognized expertise, qualified research technicians, and key industry contacts, all with proven track records of success. Building upon the successful blueprint established by the Japan National Cancer Center's (JNCC) Center for Medical Genomics located in Tsukiji, Japan, and the expansive research that resulted from the five year Millennium Genome Project (concluded in March 2005), Eurus has stepped in to continue and expand this effort at its state-of-the-art research facilities in Hawaii. In addition to its natural beauty, Hawaii has many unique qualities such as ethnic diversity, island topography, and medical partnerships creating an ideal setting to cultivate the efforts initiated in Japan. Additionally, there are many multi-generational Japanese families that provide a bridge for the existing research as well as expansion into other ethnic backgrounds for future studies.

At Eurus's laboratories in Japan and Hawaii, research and development is ongoing striving to discover the inherited differences, or genomic markers, that exist within human genes. Eurus,

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in conjunction with its research partners at the JNCC and NCI, has made significant progress in pharmacogenomics -- the identification of genomic markers that define a patient population in terms of the best-anticipated response to medication while maintaining the highest level of patient safety. Advances in pharmacogenomics hold out the promise of individualized treatments, specifically tailored to an individual's unique biological makeup.

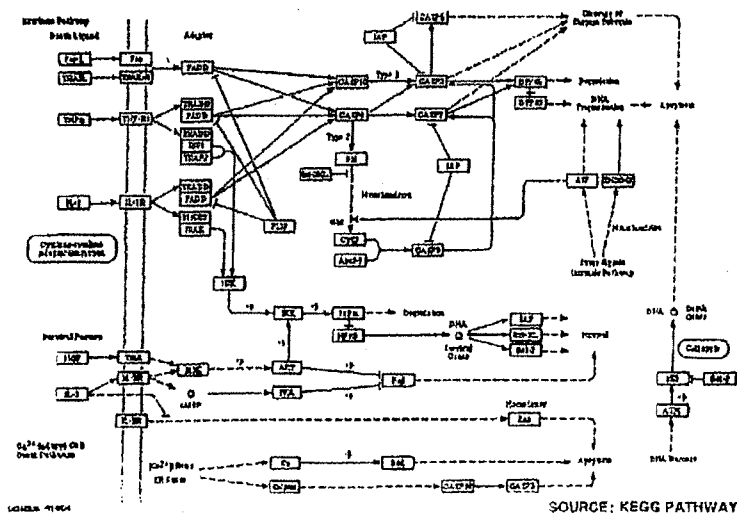
Of particular significance, Euris and its partner researchers have developed a proprietary algorithm that enables the rapid processing of vast quantities of genomic data and the identification of unique genetic markers. The algorithm and essential elements of the process have been patented. Our validation studies, using known data sets, have not only validated our methodology; it has demonstrated its superiority to the existing and accepted methodologies.

## 2.2. Genesys Technologies, Inc



Genesys Technologies, Inc. (GTI) was established May 2002 and has focused its efforts on the identification of critical genetic markers. Of particular significance, GTI developed an algorithm that enables multi-factorial inheritance analysis. Pre-existing algorithms are unable to calculate haplotypes of more than 32 SNPs. GTI's breakthrough technology enables the calculation of nearly infinite numbers of haplotypes. To date, GTI has identified the gene associated with efficacy/toxicity of methotrexate (associated gene MTHFR) and sulfasalazine (associated gene: NAT2) and has made significant progress in identifying the genes associated with leflunomide (Arava™) and infliximab (Remicade™) efficacy/toxicity.

### GTI's Current Pathway Focus



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#### 2.2.1. Clinical Laboratories of Hawaii, LLP



ANTARA partner Clinical Laboratories of Hawaii, LLP ("CLH"), is registered with the FDA as a CLIA approved-laboratory. CLH provides a critical foundation for the Company's path to market (as an ASR) and to FDA approval.

Founded in 1971, CLH is the state's leading diagnostic laboratory provider. Servicing 14 out of the 24 civilian acute care hospitals in Hawaii, CLH provides 44 percent of the inpatient laboratory services and operates over 40 outpatient service centers throughout the state. CLH has consistently provided its customers with high-quality, timely and accurate services, using innovative and cost-effective technology. With over four hundred professional, technical, and support personnel, Clinical Laboratories of Hawaii has expertise in every laboratory discipline including:

- Immunogenetics
- Cytology
- Forensic medicine
- Surgical pathology
- Blood banking
- Infectious diseases
- Toxicology
- Neuropathology
- Pediatric pathology
- Gynecologic pathology

CLH aggressively recruits staff from the nation's leading medical centers, including the Mayo Clinic, University of California San Francisco, University of Minnesota and Walter Reed Army Medical Center. All pathologists are board-certified in both anatomical and clinical pathology. Many have sub-specialty board certification in such areas as blood banking, forensic pathology and cytopathology.

CLH and its affiliate, Pan Pacific Pathologists, Inc., abide by federal and state regulations governing clinical laboratory testing and patient confidentiality. Our testing sites are either CAP or CLIA accredited and our testing sites located in Health Care Facilities abide by JCAHO standards.



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### 2.3. Management Team

ANTARA will be lead by an experienced and diverse management team that has proven success in all aspects of the biotech industry, and particular expertise in laboratory instrumentation, gene chip technology, molecular biology, molecular biophysics, immunology and *in vitro* diagnostics.

Position	Individual	Representative Experience/Credentials
CEO	Marc R. Labgold, Ph.D.	Caltech; Industry-Wide Consulting/ Representation; Patton Boggs
President	Dana Ichinotsubo	Eurus Japan; U. Hawaii Medical
COO	[confidential]	Affymetrix; Perlegen
CSO	[confidential]	Roche Molecular Diagnostics; Bayer Chiron
CFO	[confidential]	
Exec. VP, Information Technologies/Bioinformatics	[confidential]	Affymetrix; Perlegen
Exec. VP, Marketing and Sales	[confidential]	Roche Molecular Diagnostics; Affymetrix
Exec. VP, Regulatory	[confidential]	Abbott Labs; Baxter Healthcare; Pfizer
General IP Counsel; Exec. V.P., Licensing	[confidential] <i>S. Brashears</i>	Clontech Labs; Perlegen; Applied Materials; Benitec

The Management Team will consist of the experts from the current *in-vitro* diagnostic industry. We have contacted various individuals and briefly discussed our proposed project. Although many are very interested we are unable to offer any specific details due to their individual confidentiality concerns. Formal negotiations and offers will follow the finalization of the licensing agreement with Toshiba. However, the diverse management and team will consist of individuals with current and past experience in the following entities:



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Roche Molecular Diagnostics, Affymetrix, Perlegen, Clontech Laboratories, ABI, Illumina, Abbott Labs, Chiron, Bayer, Baxter Healthcare, Stanford University to name a few.

#### 2.4. Advisors

##### 2.4.1. Intellectual Property and Regulatory Representation

The Company has retained Patton Boggs, LLP to assist in its successful entrance into the molecular diagnostics market and to provide key legal services.

###### Firm Overview



Patton Boggs began as an international law firm concentrating in global business and trade. Founded in 1962 by James R. Patton, Jr., and joined soon after by George Blow and then Thomas Hale Boggs, Jr., the firm has maintained its strong concentration in international and trade law with over 200 international clients from over 70 countries. Patton Boggs is recognized as the nation's leading public policy law firm, and a pioneer in merging public policy expertise with traditional legal practice. The Company has retained the firm to obtain the benefits of its undisputed leader in public policy, regulatory and intellectual property law. Working closely with the Company's leadership team, Patton Boggs is coordinating intellectual property, legislative, and regulatory strategies to promote ANTARA's market entry and success.

###### Intellectual Property

Patton Boggs' is a recognized leader in biotech, pharmaceutical, chemical and medical device patent law. The firm regularly provides expert consultation to law firms and corporations on patent law and biotechnology issues and routinely advises and represents clients on a wide range of intellectual property issues that are essential to the Company's business, including branding, patent prosecution, portfolio development, opinions, licensing, trade dress, trade secret, Lanham Act claims, advertising, design patents and trademarks.

ANTARA has retained the firm to assess the strength of the Company's existing patent portfolio, to expand that portfolio, and to assist in the development of an effective licensing policy and enforcement strategy. Patton Boggs has performed freedom-to-operate opinions with respect to the Company's intended products and services and is coordinating the expansion of the existing patent portfolio. ANTARA presently has the dominant patent position in electrochemical chip technology, affording it market exclusivity. The Company intends to diligently expand and enhance its portfolio.

Patton-Boggs has already conducted a detailed review and assessment of the Company's patent portfolio. In accordance with the Company's business objectives,

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the firm has initiated an aggressive effort to expand the Company's portfolio with the goal of securing additional market exclusivity.

**Regulatory Counsel**

ANTARA has retained Patton Boggs to lead its progress with respect to regulatory issues, including FDA approval of its products and services. Patton Boggs has extensive experience in representing manufacturers of both human and animal drugs and biologics on a wide array of issues. In the drug area, these include compliance with Investigational New Drug (IND), New Drug Application (NDA), and Good Manufacturing Practice (GMP) regulations; monograph requirements for over-the-counter (OTC) drugs; abbreviated new drug application (ANDA) requirements for generic drugs; homeopathic drug requirements; drug exports; the availability of exclusive marketing rights under the Orphan Drug Act, Hatch-Waxman Act laws and regulations, patent restoration; pediatric laws and regulations; drug reimbursement issues; restrictions on drug sampling and distribution under the Prescription Drug Marketing Act of 1988; implementation of the Prescription Drug User Fee Act; and labeling and advertising issues affecting both Rx and OTC drugs. The routinely represents individual clinical investigators and Institutional Review Boards (IRBs) on matters involving clinical investigations and compliance with all of the FDA's bioresearch monitoring requirements.

The firm also counsels manufacturers of biological products on all aspects of compliance associated with the safety, purity, and potency requirements of the Public Health Service Act and all matters pertaining to biologics licensure. In addition, the firm counsels clients on compliance with the requirements of the Federal Food, Drug, and Cosmetic Act applicable to biologics, including all IND requirements, FDA policies applicable to biologics advertising and promotion both pre- and post-approval and FDA enforcement under this law.

Patton Boggs is particularly active in legislative and public policy matters affecting the drug and biologics industry, representing clients in a wide array of sophisticated public policy matters, including but not limited to issues associated with drug safety, pricing, importation, and reimbursement.

**3. Business Overview**

**3.1. Products**

ANTARA's business is built upon patented electrochemical DNA chip technology coupled with state-of-the-art electronic instrumentation designed by Toshiba – a worldwide leader in electronics. This novel proprietary platform provides accurate *in vitro* diagnostic analysis in environments as diverse as clinical laboratories and food inspection lines. The patented Genelyzer™ system provides a simple and accurate platform with a sensitivity level that rivals or exceeds currently available detection methods

DNA chips are increasingly used as a research tool to analyze single nucleotide polymorphisms (SNPs) and the expression of messenger ribonucleic acid (mRNA). Recent



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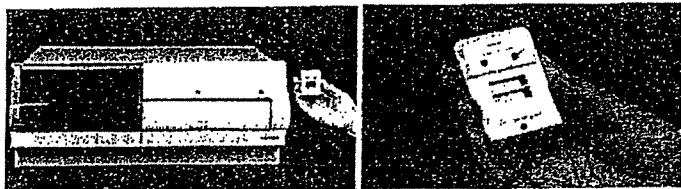
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research indicates that analysis of the copy number of mRNA is more efficient in predicting susceptibility to anticancer drugs and indicating prognostic implications. However, advances in this area have been hindered by the fact that expression analysis requires more accurate, sensitive and reproducible technology that can support quantitative determination. Simplified genetic expression analyses using DNA chip system will open up new genetic testing market, targeting not only patients but also healthy individuals.

Conventional methodologies for nucleic acid detection/analysis, including DNA-chip-based systems, commonly employ fluorescence detection. These traditional chip technologies are severely limited by the fact that the five basic processes involved in nucleic acid detection and analysis -- DNA extraction, amplification, hybridization reaction, detection and identification -- requires dedicated, expensive equipment and complex manual handling, all of which confine testing to special facilities, such as clinical laboratories. Amplification of the signal itself has failed to increase sensitivity as contaminating background interference is amplified as well. Moreover, the high degree of complexity and high costs of fluorescence-based detection are not matched by the accuracy of the analysis. The overall result is to limit the effectiveness and application of DNA testing.

A 2004 review article in *Analytical Bioanalytical Chemistry*, Vol. 378: 104-118, details the advances that have been made to date. Despite the high number of articles cited (186), the reviewers conclude that "great potential of electrochemical devices in [nucleic acid] analysis has been demonstrated," but that significant advances are still required to achieve the requisite sensitivity and to overcome the "traditional reluctance of routine laboratories to use electrochemical techniques."

The Company's technology fully addresses and overcomes the failings of existing methods and fulfills the clearly identifiable long-felt need in the molecular diagnostics field. The Company's patented technology provides extremely high sensitivity in an easy to use rapid diagnostic system. Unlike start-up companies, ANTARA makes its market entrance with a state-of-the-art computer-controlled system designed and engineered by Toshiba.



The Genelyzer™ system is based on the Toshiba's breakthrough work and basic patents in electrochemical DNA detection. At the heart of the system is an electrochemical DNA chip that is capable of one of the single most difficult challenges in the *in vitro* diagnostic field -- analyzing and typing single nucleotide polymorphisms (SNPs). SNPs are DNA sequence variations that can be used to identify genetic mutation, disorders and/or predisposition to certain conditions and/or disease states. However effective typing and analysis requires a degree of sensitivity rarely achieved with conventional techniques.

The Genelyzer™ system's effectiveness in SNP typing has been proven by independent research laboratories including the National Cancer Center Research Institute (Tokyo, Japan),

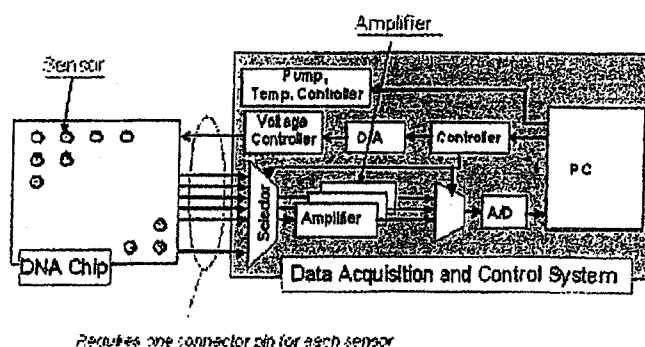
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Kobe University School of Medicine (Kobe, Japan), Tokyo Women's Medical University (Tokyo, Japan) and the GeneCare Research Institute (Kanagawa, Japan).

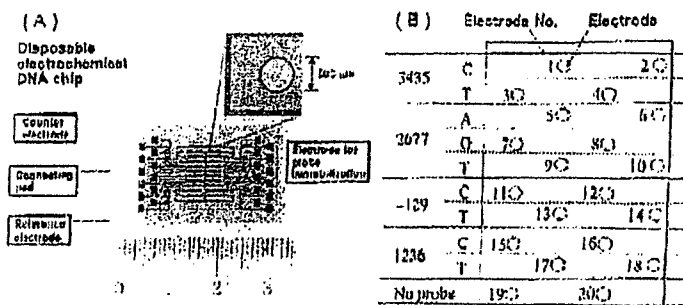
Toshiba's research and development efforts began in the early 1990's, resulting in several publications in peer-reviewed international journals and the filing of the seminal patent applications in this area. Toshiba announced its first electrochemical DNA chip in October 2001, a device that used an original current detection method to support development of individual treatment regimes for patients infected with hepatitis C. (K. Hashimoto & Y. Ishimori, *Royal Soc. Chem.*, 2001, I, 61-63).

Toshiba's R&D efforts have resulted in a diagnostic system that meets or exceeds currently available detection methods. The current (1<sup>st</sup> Generation) chip design consists of DNA probes immobilized to gold electrodes on a "chip."

System Diagram: First Generation Chip Design

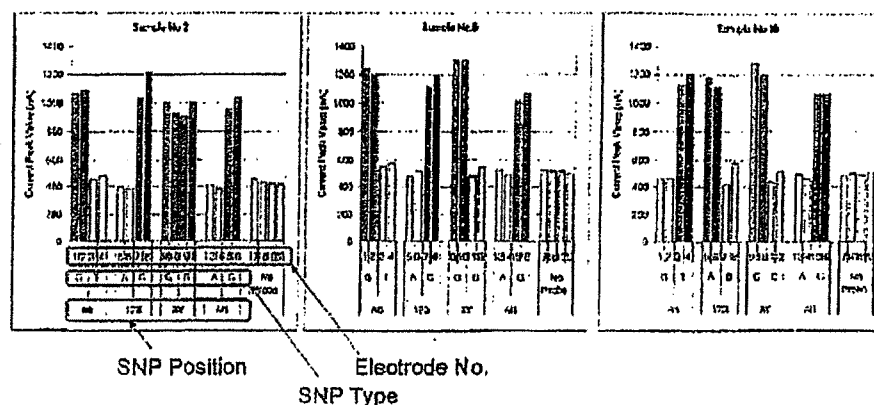


The current chip designs include 20 target and 40 target configurations. A representative example of a 20-target chip is shown below:



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Utilizing the foregoing chip configuration, the simultaneous determination of SNPs of the MDR1 gene (a gene involved in drug metabolism) has been achieved, with the results being published in 2005. (T. Nakamura *et al.*, *Drug Metab. Pharmacokinet.*, 20 (3), 219-225 (2005)).



Toshiba continued to promote R&D in this important area of optimized personal medication regimes, and in July, 2005 announced a DNA chip that supports pharmacogenomics that was jointly developed with a team from the Graduate School of Pharmaceutical Sciences of Osaka University, led by Professor Junichi Azuma. That chip supports investigation of treatment efficacy and side effects for individual patients, covering six areas of illness: tuberculosis, digestive disorders, adenoma, hyperlipemia, cardiac arrest and cancer.

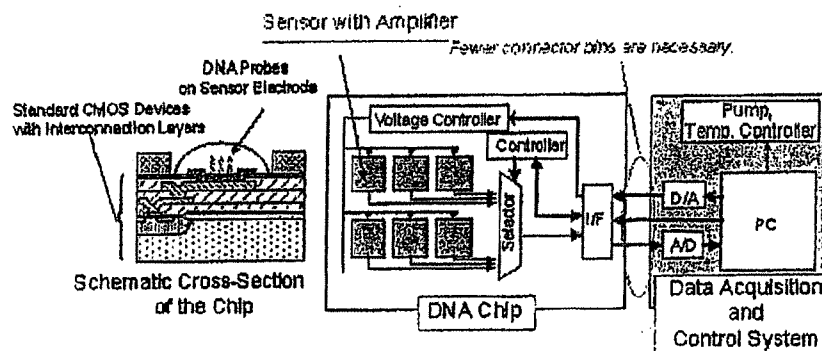
ANTARA's initial product launch will be based upon Toshiba's proven 1<sup>st</sup> Generation DNA chip. Because the fundamental reliability and sensitivity has been demonstrated, the Company expects to receive significant positive market response. (A timeline of projected milestones is provided in Section 10, below). The present design has achieved a detection sensitivity of as low as 1 copy of target nucleic acid per microliter of sample (1 copy/ $\mu$ l). The Company will initiate discussion with several key participants in the *in vitro* diagnostic market, with the intended goal of licensing its open platform system in order to secure rapid market penetration and market share. The Company presently intends to offer (alone or in conjunction with third parties) one or more analyte specific reagent (ASR) products in 2006. (See, Section 8.4, for a discussion of ASR and regulated IVD products). The Company intends to pursue FDA approval for an IVD product as early as 2007.

Concurrent with its market entry, the Company will continue Toshiba's R&D efforts in the development of a 2<sup>nd</sup> Generation chip that incorporates a dedicated complementary metal oxide semiconductor ("CMOS") signal-detection circuit in each target sensor. The use of a CMOS detection interface has resulted in the reduction of signal loss due to external noise, even when the detected signal is low - i.e., the target molecule is present in extremely low

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concentrations. This new chip design enables on-chip amplification of the signal prior to transmission, the process where most noise interference occurs in amplified signaling systems. The robust performance achieved by this novel CMOS chip enhances the system's ability to perform quantitative analysis of DNA at much lower concentrations – a theoretical increase in sensitivity of 3-5 orders of magnitude or 10 copies of target nucleic acid per nanoliter (10 copies/nl), make the CMOS DNA chip the most sensitive detection device of its kind. The CMOS circuitry has enabled quantitative analysis at previously unattainable levels of sensitivity without the need for any DNA amplification, regardless of sample type or origin.

**System Diagram: 2<sup>nd</sup> Generation CMOS-based Chip Design**



Additional design advantages in the 2<sup>nd</sup> Generation chip include signal-detecting circuits integral to the chip substrate, an approach that reduces the overall size of the equipment. Similarly, integration of selector circuitry on the chip, as opposed to the analyzer, has enabled a reduction in the number of output terminals on the chip, thereby increasing the number of analyses per chip, reducing the cost of the overall process.

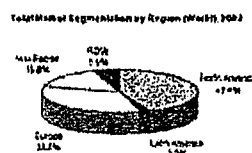
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#### 4. Market Analysis Summary

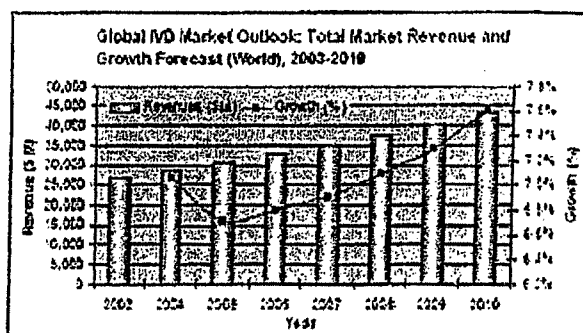
Worldwide revenues for *in vitro* diagnostic ("IVD") products and services exceeded \$28 billion in 2004. The United States continues to lead the overall IVD market, with revenues reaching nearly \$12B in 2004.

##### 2004 Global IVD Market Overview

- \$28.88 Billion in Total IVD Revenues for 2004
- US Consistently Dominates the IVD Market
  - \$11.54 Billion in Revenues
  - 41.6% Share of Global Market
  - Comda has 1.6% Share
- Europe is 2<sup>nd</sup> Largest
  - \$9.69 Billion in Revenues
  - 33.5% Share of Global Market
  - Germany is the Market Leader
- Asia Pacific Trails as 3<sup>rd</sup>
  - \$4.31 Billion in Revenues
  - 15.0% Share of Global Market
  - Dominated by Japan



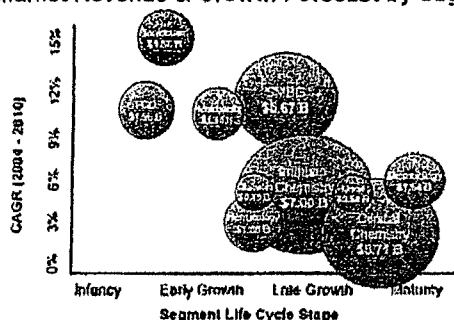
The global revenue forecast for the IVD market has been and is predicted to continue to be strong with revenues expected to steadily increase. Current forecasts estimate worldwide revenues in the IVD market to approach \$45B by 2010.



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The most significant growth is presently observed in the molecular diagnostics, self-monitoring blood glucose (SMBG), and point of care (POC) market segments. With the improvement in the quality of healthcare and increase patient access to adequate health care, there is an increase in average life expectancy, resulting in one of the fastest growing segments in the overall health-care industry being the aging population. This factor has particular significance to the cancer detection segment of the molecular diagnostics market. The molecular diagnostics market segment is currently the fastest growing segment of the IVD market - a current growth rate in excess of 15% per year.

Market Revenue & Growth Forecast by Segment



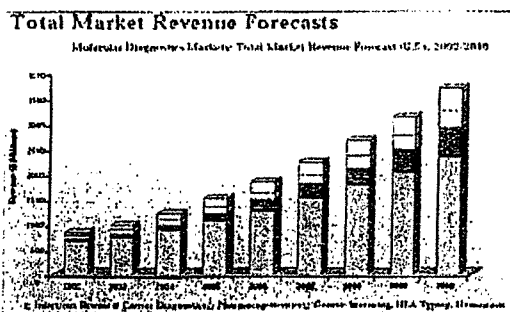
The Company's technology is particularly suited for entrance into the molecular diagnostics market due its DNA-based architecture. The Company intends to market and sell its products and services directly to pharmaceutical, biotechnology, agrichemical, and diagnostics companies, as well as clinical reference laboratories. Additional market opportunities exist in the areas of academic research, government research and private research foundation laboratories.

While the Company envisions a global reach, the Company intends to focus its initial efforts on the U.S. market. ANTARA holds exclusive rights to develop, market and sell the Genelyzer™ products in the United States. ANTARA also has, and will continue to develop, its own intellectual portfolio for which it will seek worldwide protection. Toshiba has presently retained the rights to market and sell the Genelyzer™ products in Japan. The Company has offered Toshiba the right to license ANTARA's improvements and/or application-based patents for the Japanese market. Such licensing could result in higher than expected revenues. ANTARA has a right of secure exclusive patent rights in additional markets.

The U.S. has and continues to lead the overall IVD market. It is estimated that the U.S. will continue to be a dominant market potential for at least the coming five (5) years. U.S. Market recognition of products and services has a strong tendency to promote acceptance in other markets.



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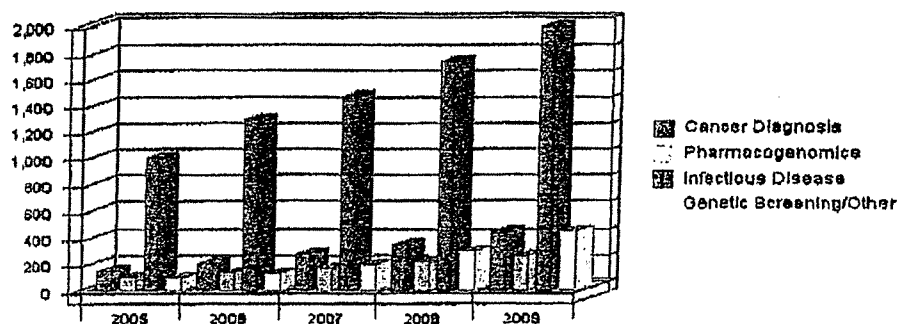


#### 4.1. Market Segmentation (U.S.)

The U.S. IVD market is presently segmented as follows:

	2005	2006	2007	2008	2009	CAGR
Potential Customers						
Cancer Diagnosis	155	210	280	350	450	30.53%
Pharmacogenomics	110	140	175	225	270	25.17%
Infectious Disease	1,000	1,300	1,475	1,750	2,000	18.92%
Genetic Screening/Other	100	130	200	300	450	45.65%
<b>Total</b>	<b>1,365</b>	<b>1,780</b>	<b>2,130</b>	<b>2,625</b>	<b>3,170</b>	<b>23.45%</b>

#### Market Segmentation Analysis



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## 4.2. Target Market Segment Strategy

### 4.2.1. Infectious Disease

Infectious disease continues to lead the *in vitro* diagnostics market by nearly an order of magnitude. While not viewed as a leading edge or technically attractive market, infectious disease will continue to be the single largest revenue generating market segment for the foreseeable future. The Company intends to leverage its inherent strengths to gain market share in this lucrative area.

The Company's open platform technology is particularly suitable for adaptation to infectious disease applications. The Company is pursuing patent applications in the areas of infectious disease diagnosis and pharmacogenomics. By combining its expertise in genomics, immunochemistry, proteogenomics and its proprietary electrochemical DNA chip technology, the company is positioned to make an early entry into the infectious disease market.

ANTARA will actively pursue novel and proprietary methods of disease detection and pharmaco-analytic methods and products, with a particular emphasis on accurate antibiotic therapies that reduce the unnecessary over-prescription of antibiotics – an all too common occurrence that has the tragic consequences of prolonged illness, antibiotic resistance and, in an increasing frequency, death due to sepsis.

### 4.2.2. Cancer Detection

#### The Company Is Uniquely Positioned to Capture Significant Market Share In The Cancer Detection Market Segment

One of the distinguishing characteristics of the present venture, is its recognized strength and expertise in the area of cancer detection. The Company has identified and holds dominant proprietary rights with respect to several key cancer markers. This factor alone provides the Company with the primary competitive advantage required for market entry and market share acquisition.

Cancer is a genetic disease, characterized by the uncontrolled growth of cells. Many forms of cancer are caused by genetic mutations acquired over the course of an individual's life - often due to exposure to some mutagenic agent. A critical factor in cancer survival, is the early detection and localization of the genetic abnormality. The key to any nucleic acid-based diagnostic is the genetic markers associated with a particular type of cancer. The following table highlights several of the recognized factors affecting cancer detection diagnostics.



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Cancer Diagnostics Market: Market Drivers Ranked In Order of Impact (U.S.), 2004-2010

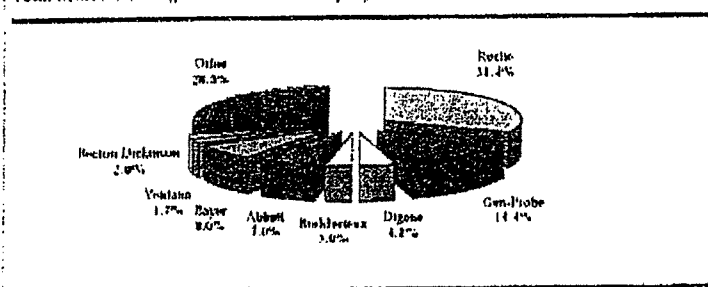
Rank	Driver	1-2 Years	3-4 Years	5-7 Years
1	Early detection is the primary factor affecting cancer survival rates	High	High	High
2	Growth of public single nucleotide polymorphism (SNP) databases aids discovery of biomarker profiles	High	High	Medium
3	Intellectual property patents allow companies to develop a niche in the competitive marketplace	High	High	Medium
4	Less-invasive molecular testing promotes patient screening	High	Medium	Medium
5	Automation increases high-throughput sample processing	Medium	High	High
6	Aging population contributes to increase in cancer rates	Medium	Medium	High

The Company's proprietary position with respect to several critical cancer markers and its ongoing expertise in marker identification is expected to result in market demand for its products/services. The Company's valuable patent portfolio provides exclusivity, thereby enabling a dominant market position in this profitable and expanding market space.

Industry analysis shows that the cancer diagnostics segment of the overall molecular diagnostics market is still in the early development stages with relatively few available technologies presently on the market. Increased life expectancy has a significant impact on the growth potential in the cancer diagnostics market due to the correlation between an aging population and an increase in cancer rates. The likelihood of developing cancer throughout one's lifetime is roughly 1 in 2 for men and 1 in 3 for women. It is estimated that 77% of new cancers are diagnosed in individuals over the age of 55.

Most available technologies remain in the development stage with primary use limited to research used only. The predominant technologies include hybridization-based methodologies for the detection of genetic predisposition or mutation. The present number of nucleic acid-based detection products remains extremely limited.

Total Molecular Diagnostics Market: Company Market Share by Revenue (U.S.), 2003



In 2004, three companies controlled nearly 80% of the total molecular diagnostics market. Key factors for the dominant position of the two leaders, and the likely key for others' successful entrance into the marketplace, are dominant patent positions and FDA approvals validating the clinical utility of their products.

Digene Corporation continues to dominate the cervical cancer diagnostics market. It remains the only company with an FDA-approved product for the early detection of cervical cancer.

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Digene's proprietary Hybrid Capture® technology involves a solution phase hybridization of nucleic acid probes specific to those types of human papilloma virus (HPV) known to cause cervical cancer, followed by the "capture" and subsequent detection of the hybridized nucleic acids by specific antibodies. The Digene tests have been automated and are widely used.

Vysis (a subsidiary of Abbott Laboratories), had a strong market entrance with its UroVysis product, which is used for the early detection of recurrent bladder cancer. The FDA-approved UroVysis product employs fluorescent in situ hybridization (FISH) probes. Vysis has also had success with its PathVysis product, which is used in HER-2/neu analysis of women having prior cancer diagnosis. This product is more properly characterized as a pharmacogenomic product rather than cancer diagnostic. It is an FDA-approved product used in the diagnosis of multiple gene copies characteristic of HER-2/neu over-expression in certain forms of breast cancer as well as prognosis with regard to treatment with chemotherapy such as Herceptin.

Ventana Medical Systems, Inc. has also had notable success in the cervical cancer detection market. In contrast to Digene, however, Ventana did not seek an FDA pre-market approval, opting instead to sell its product as an analyte specific reagent (ASR). (See Regulatory Approval section below). Because of its ASR status, the distribution of Ventana's in situ hybridization products is limited to CLIA clinical laboratories. Ventana's business has been marred by patent infringement litigation and its need to acquire licenses to practice much of its technology. Its instrument systems were recently taken off the market after a determination of infringement.

While nucleic acid arrays hold significant promise in the detection of nucleic acid based predisposition, its application in widespread use has been restricted by intellectual property portfolio of Affymetrix, Inc. The use of these so-called "DNA chips" has for the most part been limited to research use only, with the notable exception being Roche's AmpliChip technology developed under a license from Affymetrix. Further complicating the chip landscape is the patents owed by Oxford Gene Technology, Inc.

The high demand for both cancer markers and a viable platform are expected to drive the Company's entry and successful participation in the molecular diagnostics market.

#### 4.2.3. Homeland Security

Antara intends to pursue several projects related to Homeland Security. In response to the terrorist attacks on the United States, the U.S. government formally instituted the Department of Homeland Security (DHS). In accordance with its mandate, DHS actively pursues new methods and technologies for the early and rapid detection of chemical and biological agents. These projects are administered through the Science and Technology Directorate (S&T). S&T is the primary research and development arm of the Department. It provides federal, state and local officials with the technology and capabilities to protect the homeland through the following strategic objectives:

- Develop and deploy state-of-the art, high-performance, low-operating-cost systems to prevent, detect, and mitigate the consequences of chemical, biological, radiological, nuclear, and explosive attacks;

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- Develop equipment, protocols, and training procedures for response to and recovery from chemical, biological, radiological, nuclear, and explosive attacks;
- Enhance the technical capabilities of the Department's operational elements and other Federal, State, local, and tribal agencies to fulfill their homeland security related missions;
- Develop methods and capabilities to test and assess threats and vulnerabilities, and prevent technology surprise and anticipate emerging threats;
- Develop technical standards and establish certified laboratories to evaluate homeland security and emergency responder technologies, and evaluate technologies for SAFETY Act certification; and
- Support U.S. leadership in science and technology.

As part of the Homeland Security Act of 2002, Public Law 107-296, Congress enacted the SAFETY Act to provide "risk management" and "litigation management" protections for Sellers of qualified anti-terrorism technologies and others in the supply and distribution chain. The aim of the Act is to encourage the development and deployment of anti-terrorism technologies that will substantially enhance the protection of the nation. Specifically, the SAFETY Act creates certain liability limitations for "claims arising out of, relating to, or resulting from an act of terrorism" where qualified anti-terrorism technologies have been deployed. It also confers other benefits. Although there are many technologies that are important to protecting our homeland, the SAFETY Act "Designation" and "Certification" are designed to support effective technologies aimed at preventing, detecting, identifying, or deterring acts of terrorism, or limiting the harm that such acts might otherwise cause, and which also meet other prescribed criteria. The current list of DHS approved products/technologies can be found at: <https://www.safetyact.gov/DHS/SAActHome.nsf/Main?OpenFrameset&67AB24>.

In addition to purchasing products, DHS provides significant funding opportunities (grants in excess of \$100M have been awarded). A sub-section of S&T that funds such programs is the Homeland Security Advanced Research Projects Agency (<http://www.hsarpabaa.com/>). Visiting this page provides a detailed listing of the contracts and awards issued to date.

DHS continues to actively seek new technologies to ensure its capabilities in early and rapid detection of chemical and biological agents. DHS is presently soliciting technologies that include:

- Rapid Suspected Bio-agent Screening - a tool and method for rapidly screening suspicious "white powders" to eliminate the probability that the substance is a biological threat agent.
- Biosurveillance Detection Algorithms - an algorithmic procedure/model to provide earliest detection of bioterrorist attacks on humans, plants, animals, food, water, or the environment based on correlations between a broad range of low confidence biosurveillance data streams.

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- Rapid Field Identification of High Priority Plant Pathogens (RFIP) - person-portable system that will provide minimally trained user's assistance in field identification of plant pathogens.
- One-Person Portable Chemical Detector - a lightweight, chemical detection device for use in ports of entry (both land and seaport environments) to simultaneously detect and identify high priority chemical threat agents and Toxic Industrial Chemicals (TICs).

Antara has several embodiments of its products, which will enable the rapid detection of chemical and biological agents (anthrax, ricin, etc.) at greater sensitivity than other available/existing technologies. Antara has several proposed products which can rapidly screen panels of no less than 40 agents using the present configuration and as many as 200 agents using contemplated embodiments. Patent applications to each of these embodiments are being prepared and/or have been filed. Antara intends to respond to the DHS requests for proposals and seek S&T certification under the SAFETY Act. If its proposal(s) is accepted, Antara will be eligible for federal funding in excess of US\$100,000,000. Antara has retained Patton Boggs, LLP, the nation's preeminent lobby and government relations law firm, to assist in its efforts to secure favorable review of its research proposals.

## 5. Implementation Summary

### 5.1 Intellectual Property

ANTARA is built upon a foundational patent position created by Toshiba. The Company has exclusive rights to Toshiba's DNA chip-related patents in the U.S. In addition, the company has exclusively licensed a comprehensive portfolio of patent applications, which supplement the existing patents and provide the Company with a broad scope of exclusivity. The Company's existing and contemplated patent portfolio provides a dominant and unique opportunity to enter this highly profitable business sector with the prospect of establishing and maintaining market exclusivity with respect to its contemplated products and services.

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## 6. Implementation Summary

### 5.2 Intellectual Property

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#### 5.2.1 Toshiba-Derived IP

##### Patents

The following is a general description of the Toshiba patents, which are exclusively licensed to ANTARA. The descriptions provided are for general informational purposes only and are not intended to limit, define or otherwise interpret the scope of the claims.

##### I. EP 0478319

European Patent 0478319 ("the '319 patent") was filed September 26, 1991 and was granted April 2, 1997. The patent claims priority to Japanese Patents 259011/90 with a priority date of September 28, 1990, 90879/91 with a priority date of April 22, 1991, and 191868/91 with a priority date of July 31, 1991.

The claims are directed to gene detection methods where a nucleic acid probe is immobilized onto an electrode, a sample containing a target nucleic acid is added so that the target and probe hybridize to each other, and to which a nucleic acid intercalating agent is added. The presence of the target is achieved by detecting the intercalating agent by electrochemical means. The method involves applying a potential to the electrode before, upon, or after hybridization of the target to the probe. The intercalating agent can be selected from such representative agents as ethidium, ethidium bromide, acridine, aminoacridine, acridine orange, proflavin, ellipticine, actinomycin D, daunomycin and mitomycin C.

Alternatively, the intercalating agent can also be a metal complex capable of undergoing an electrically reversible oxidation-reduction reaction, provided the oxidation-reduction potential of the metal complex is less than the oxidation-reduction potential covered by the nucleic acid. The claimed methods also include the use of an intercalating agent that has a bound substance capable of generating an electrical signal detectable directly or indirectly by the electrode. The probe nucleic acid can be immobilized onto the electrode by an amino group or through a film. The electrode is also covered with surfactants, fatty acids and fats. The method also covers the use of an intercalating agent that

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can be detected by electrochemiluminescence with a photo detector separate from the electrode.

II. US 5,776,672

US Patent No. 5,776,672 ("the '672 patent") was filed December 16, 1993 and was granted July 7, 1998. The patent claims priority back to Japanese Patents 259011/90 with a priority date of September 28, 1990, 90879/91 with a priority date of April 22, 1991, 191868/91 with a priority date of July 31, 1991, and a US Application Serial No. 766,064 filed September 27, 1991, now abandoned.

The claims are directed to a gene detection method where a nucleic acid probe is immobilized onto an electrode, a sample containing a target nucleic acid is added so that the target and probe hybridize to each other, and a nucleic acid recognizing agent is added. The recognizing substance can be an intercalating agent. The presence of the target is achieved by detecting the intercalating agent by electrochemical means. The method involves applying a potential to the electrode upon hybridization of the target to the probe. The intercalating agent can also be a metal complex capable of undergoing an electrically reversible oxidation-reduction reaction, provided the oxidation-reduction potential of the metal complex is less than the oxidation-reduction potential covered by the nucleic acid. The method also covers an intercalating agent that has a bound substance capable of generating an electrical signal detectable directly or indirectly by the electrode. The recognizing substance can also be a biopolymer that binds specifically to a double stranded nucleic acid. The probe nucleic acid can be immobilized onto the electrode by an amino group or through a film. The electrode is also covered with surfactants, fatty acids and fats as insulation means, presumably in order to reduce any background.

III. US 5,972,692

US Patent No. 5,972,692 ("the '692 patent") was filed June 30, 1997 and was granted October 26, 1999. The patent is a divisional application of the '672 patent and claims priority back to Japanese Patents 259011/90 with a priority date of September 28, 1990, 90879/91 with a priority date of April 22, 1991, and 191868/91 with a priority date of July 31, 1991.

The claims are directed to a gene detection device which comprises a single stranded nucleic acid probe immobilized on an electrode, a reaction vessel in which the sample can be reacted with the probe to hybridize to the probe, a washing means to remove the unreacted sample after hybridization of the sample and the probe, and a detection vessel to store a substance which binds specifically to double stranded nucleic acid and is physiochemically active in the reaction system of the probe and the target nucleic acid. The device further comprises a sample purification means for denaturing the sample to a single



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stranded form. The reaction vessel can be divided into a plurality of vessels to allow multiple samples to be analyzed simultaneously. The device further comprises a means for transporting the electrode and a means for controlling the temperature of the sample. Additionally, the device comprises a dissociation means to dissociate the target from the probe to regenerate the probe on the electrode.

IV. US 6,489,160

US Patent No. 6,489,160 ("the '160 patent") was filed February 26, 2001 and was granted December 3, 2002. The patent claims priority back to Japanese Patent Application 2000-074490 with a priority date of March 16, 2000.

The claims are directed to a method of producing an immobilized nucleic acid probe carrier comprising immobilizing a first nucleic acid strand on a first substrate, synthesizing a second strand that is complementary to the first strand in a nucleic acid synthesizing solution, introducing a second substrate so that the second substrate faces the side of the first substrate that has the first nucleic acid strand, applying an electric field to the first substrate to cause the migration of the synthesized second nucleic acid strand to the second substrate, and immobilizing the second strand on the second substrate. The migration of the second strand is carried out in an electrolytic solution and the electric field is applied to the substrate by having a pair of electrodes outside the first and second substrates. The substrate can be a polymer or glass. Alternatively, the substrates are themselves conductive and applying a potential to the substrate generates the electric field. If the substrates are conductive they can be prepared by coating an insulator substrate with a conductive film that has been divided into a plurality of isolated electrode regions by insulation layer patterns, and the isolated electrode regions that have the immobilized first and second strands have different sequences. The nucleic acid strands can be DNA, RNA, PNA and analogues of these. Additionally, the bonding of the second nucleic acid strand to the second substrate can be selected from the group consisting of covalent bonds, affinity bonds, or electrostatic bonds. Further, the surface of the second substrate can comprise gold and the bond between the second substrate and the second strand is an affinity bond between sulfur in the second strand and the gold. The synthesis solution of the claims comprises a primer, a nucleic acid synthesis enzyme, a nucleotide monomer and an electrolyte and the dissociation step comprises a temperature of over 90°C for the electrolyte solution.

V. US 6,667,155

US Patent No. 6,667,155 ("the '155 patent") was filed March 21, 2001 and was granted December 23, 2003. The patent claims priority back to Japanese Patent

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Applications 2000-080955 with a priority date of March 22, 2000 and 2001-062372 with a priority date of March 6, 2001.

The claims are directed to a method of predicting the efficacy of interferon therapy for treating an individual with hepatitis C. The claims require detecting hybridization to specific sequences of nucleic acid that are immobilized on a base. The method can encompass labeling the polynucleotide sample taken from the individual to be tested with a fluorescent dye, a hapten, an enzyme, a radioisotope, or an electrode active substance. Additionally, if the base to which the immobilized probe is attached is a conductive substance, the method can employ detecting an electrochemical change accompanied with hybridization where the detection involves measuring the electric signal generated between the base and a counter electrode when voltage is applied between the base and the counter electrode.

VI. US 6,670,131

US Patent No. 6,670,131 ("the '131 patent") was filed November 29, 2001 and was granted December 30, 2003. The patent claims priority back to Japanese Patent Application 2000-364614 with a priority date of November 30, 2000.

The claims are directed to a method of electrochemically detecting the presence of nucleic acids comprising first and second vessels where the second vessel has a counter electrode on the bottom or an inside surface and contains a nucleic acid binding solution, inserting into the first vessel the target nucleic acids and a stick-like electrode having multiple electrodes with immobilized nucleic acid probes attached to an electric circuit, conducting a hybridization reaction in the first vessel, taking the immobilized electrode from the first vessel and inserting in the second vessel, applying a predetermined voltage between the immobilized electrode and the counter electrode so as to measure electrochemical signals generated due to the nucleic acid binding reagent solution, and selecting one of the signals by the circuit to determine one of the plurality of the target nucleic acids. The circuit comprises an active matrix system including MOSFETs. A hybridization promoter can be used during the hybridization reaction and a voltage can be applied to the immobilized electrode to promote hybridization. This appears to address the omission, or lack of claim coverage identified in the '672 patent. Thus, the attractive, marketable quality of fast hybridization by regulating the voltage during the hybridization reaction may be covered and the right to exclude others from the market seeking to perform this method may exist. The claimed method requires that the nucleic acid binding solution acts on coupling between nucleic acid probes and target nucleic acids to generate electrochemical signals.

The claims also cover a nucleic acid detection apparatus for electrochemically detecting the presence of nucleic acids. The apparatus comprises a stick-like immobilized nucleic acid electrode with multiple electrodes and multiple nucleic acid probes immobilized to the multiple electrodes, a first electrical



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circuit connected to the multiple electrodes configured to select one of the electrochemical signals to be generated, a vessel to bring the target nucleic acids and the probes in contact with each other, a counter electrode formed on the bottom surface or inside the vessel, and a second electrical circuit configured to apply a voltage between the immobilized electrode and the counter electrode. Additionally, the apparatus can have two electrodes on the bottom or inside surface of the vessel, one to be used as a counter electrode, the other to be used as a reference electrode.

**VII. US 6,783,935**

US Patent No. 6,783,935 ("the '935 patent") was filed March 22, 2001 and was granted August 31, 2004. The patent claims priority back to Japanese Patent Applications 2000-080955 with a priority date of March 22, 2000 and 2001-062372 with a priority date of March 6, 2001.

The claims are directed to the sequence of polynucleotides that can be used to predict the efficacy of interferon treatment of individuals suffering from hepatitis C. The claims also cover vectors comprising the sequence of the claimed polynucleotides. The polynucleotides can be the claimed sequence or the complement of the sequence. Additionally, the polynucleotides can further comprise at least one more polynucleotide attached to the sequence. The attached polynucleotide can be selected from the group consisting of a promoter, an enhancer, an upstream activation sequence, a silencers, a upstream suppression sequence, an attenuator, a poly A tail, a nucleus transport signal, a Kozak sequence, an interferon response element ("ISRE"), a drug resistance factor, a gene of signal peptide, a gene of Tran membrane domain, a gene of marker protein, a gene of interferon-responding protein, and a gene of interferon-non-responding protein.

**VIII. US 6,818,109**

US Patent No. 6,818,109 ("the '109 patent") was filed September 25, 2001 and was granted November 16, 2004. The patent claims priority back to Japanese Patent Application 2000-301516 with a priority date of September 29, 2000.

The claims are directed to a nucleic acid detection sensor comprising a plurality of nucleic acid chain fixed electrodes each with a nucleic acid probe attached, a reference electrode on the same plane as the nucleic acid chain electrodes, and a counter electrode opposite to and surrounding the nucleic acid electrodes so that a current can flow between the counter electrode and each of the nucleic acid electrodes. Alternatively, there is a counter electrode for each nucleic acid electrode. The nucleic acid electrodes and the counter electrode are arranged so that a liquid can flow between them, this then allows a current change caused by the hybridization of the probe nucleic acid and a

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nucleic acid present in the test sample liquid to be detected. Moreover, additional claims cover a duplex chain cognitive body added to the test liquid to cause the current change.

Further, the claims cover mutual engagement of the nucleic acid electrodes, counter electrodes and reference electrodes, which can be comb electrodes, *i.e.*, they can occupy the same space and orientation in the vessels. The sensor can also have a first amplifier that inputs a signal from the reference electrode or scanning line, a second amplifier that applies a predetermined potential to the counter electrode, and a reference resistor connected between the output side of the first amplifier and the reference potential. Additionally, the sensor can have a plurality of scanning lines configured to transmit separately a select signal that selects more than one of the pluralities of nucleic acid electrodes. The claims also cover a plurality of scanning lines each configured to transmit one by one a select signal that selects more than one of the plurality of nucleic acid fixed electrodes a plurality of signal lines configured to transmit a measurement signal from the plurality of nucleic acid electrodes and a plurality of switching elements connect it with the plurality of nucleic acid electrodes the plurality of scanning lines and the plurality of signal lines. The switching elements are configured to turn on and turn off a connection between the plurality of nucleic acid electrodes and the plurality of signal lines according to select signals from the plurality of scanning lines and provide it for the nucleic acid on electrodes.

The claims also cover a decoder connected to the plurality of scanning lines and timing pulse generator configured to generate a clock signal and a counter configured to connect the timing generator with the decoder. Additionally, the sensor comprises a plurality of A/D converters each connected to the plurality of signal lines and may also include a plurality of amplifiers connected between the signal lines and the A/D converters. Alternatively, the sensor comprises a plurality of transistors each connected to the plurality of signal linings and a common A/D converter connected to the plurality of signal linings via the plurality of transistors further the sensor may have a plurality of amplifiers connected between the plurality of nucleic acid electrodes in the plurality of transistors. Moreover, the plurality of signal lines are covered with insulation films.

IX. US 2005/0048558

This application was filed October 5, 2004 and was published March 3, 2005. This is a divisional application of the '109 patent. The published application has forty-eight pending claims. The claims are directed to a method of detecting nucleic acids by contacting a test liquid to a nucleic acid detection sensor. The sensor is the sensor described in the '109 patent. The method requires performing a hybridization reaction between the probe nucleic acid chains and nucleic acid chains in the test liquid, and measuring electrochemical

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signals flowing between the nucleic acid electrodes and counter electrode. The measuring of the electrochemical signal includes detecting a current change between the nucleic acid electrodes and the counter electrode.

X. US 2005/0095637

This application was filed November 19, 2004 and was published May 5, 2005. This is a divisional application of the '109 patent. The published application has fifty pending claims. The claims cover a nucleic acid detection sensor as described in the '109 patent with the additional limitation that each of the nucleic acid electrodes and the counter electrode has a flat plane and that the flat plane of one of the nucleic acid electrodes is arranged to face the flat plane of the counter electrode.

XI. US 2005/0100909

This application was filed August 5, 2003 and was published May 12, 2005. This is a divisional application of the '155 patent. The published application has twenty-eight pending claims. The claims cover a carrier for gene detection comprising a base with a polynucleotide immobilized on the base body. The polynucleotide is selected from a list of sequences specific for the ability to predict an individual's response to interferon therapy for treatment of hepatitis C and is further limited to a length between 15 and 30 bases. The claims cover a carrier that is used as an electrode. The claims also cover a DNA chip comprising a base body that has first and second electrodes, where one of the polynucleotide sequences is immobilized on the first electrode, and a different polynucleotide sequence is immobilized on the second electrode, where both sequences immobilized are limited to 15 to 30 bases in length. The claims also cover a method of detecting the validity of interferon therapy in an individual by measuring an electrochemical change accompanying hybridization of the target to the immobilized probe. This electrochemical change is measured by the electrical signal generated between the carrier for gene detection and a counter electrode when a voltage is applied between the carrier and the counter electrode. This change can be augmented by the use of a double strand recognizing substance that can generate the electrical signal either directly, or, indirectly. The claims also cover a method of detection involving labeling either the probe polynucleotide or the polynucleotide contained in the test sample.

Additional claims cover a gene detection apparatus comprising the carrier for gene detection, a counter electrode, a voltage application means, a reaction section in which to conduct the hybridization reaction, and a measurement section for measuring the electrical signal generated. Further claims cover a kit for detecting the validity of interferon therapy which comprise the carrier for

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gene detection with the specific sequences immobilized, a buffer solution, and may or may not have a double strand recognizer.

#### Trademarks

The Company has secured the right to use Toshiba's name and other associated trademarks in conjunction with the marketing and sale of the Genelyzer products and services.

#### 5.3 Euris-Derived IP

In addition to its established team of research experts, research technicians, and key industry contacts, Euris provides valuable intellectual property to the Company.

#### 5.4 Patents

Nucleic acid detection by electrochemical means first emerged at the beginning of the 1990s. Most nucleic acid detection relies on detecting hybridization of complementary sequences, electrochemical detection means also rely on this detection of hybridization. With electrochemical detection of nucleic acids, the most preferred method involves a probe immobilized on the surface of an electrode. These probes are generally synthetic pieces of nucleic acid, or oligonucleotides, but the nature of these nucleic acids can affect the detection of a target. For example, the use of Peptide Nucleic Acid ("PNA") allows for a more stable PNA-DNA duplex at higher temperatures and lower salt concentration, and can provide more specific recognition of single base mutations. The structure of the immobilized probe can also be a factor influencing detection. For example, electrochemical nucleic acid hairpins have a self complimentary sequence at both ends, have a label at one end, and in the presence of a fully complementary target, the hairpin opens, resulting in a change in the redox response of the label. Commercial embodiments of this may be attractive to potential customers, as there may be benefits in the detection of target sequences.

Further, the method of immobilizing these probes on the surface of the electrode, for example, adsorption, film entrapment, affinity binding, chemisorption, or covalent bonding, can have a significant affect on the ability to detect fully complementary sequences and to avoid any background signal. Similarly, the method of detecting the hybridization can affect the sensitivity and are split into direct and indirect methods. Direct methods include oxidation of nucleotides, catalytic oxidation of sugar moieties, and photoelectroactivity of nucleic acids, but considerations such as the bases in the probe, *e.g.*, guanine, inosine and other analogues, affect the sensitivity and background noise. Indirect methods include the use of covalently bound markers, use of hybridization indicators, *e.g.*, electroactive intercalators to amplify the signal, capacitance and impedance at the electrode surface, conductivity of bilayer membranes, and changes in conductivity of polymers. Therefore, many individual components of the detection method and any apparatus used in a detection method can have a significant affect on the ability to detect the target in a fast, simple, and cost effective manner. Accordingly, many different variables affecting probe composition and signal amplification may become commercially attractive and the protection of these

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commercially preferred embodiments should be pursued. However the ability to secure such patent coverage is unpredictable.

Eurus has secured the exclusive rights to patent applications directed to:

- a. Generic Ab applications (~3-4)
- b. New linker chemistry
- c. Specific target detection (~10)
- d. Real-time detection methods
- e. Alternate chip configurations
- f. Laser-directed surface patterning
- g. Solution phase hybridization chemistry

These applications will be exclusively licensed to the Company within its intended business areas.

#### 5.5 Trademarks

The Company has secured the right to use Eurus' name and other associated trademarks in conjunction with the marketing and sale of its products and services.

### 6.0 Weaknesses

#### 6.1. Required Product Improvement

##### 6.1.1. Chemistry

Despite the critical advancements to the field of *in vitro* diagnostics that the Genelyzer products represent, the current configurations suffer from certain weaknesses, which the Company intends to address. For example, the current linking chemistry (*i.e.*, the manner in which the nucleic acid probes are immobilized to the electrochemical chip, is not entirely compatible with the chemistry employed in standard automated DNA synthesis instruments. As such, the time required to prepare the oligonucleotides can be as much as 3 weeks. The Company has secured exclusive rights to modified chemistry methodologies which are expected to reduce this time to as little as several days, however, process optimization will be required.

Other technical issues do exist and the Company has developed or secured the rights to address these issues. However, the time required for implementation and optimization is difficult to predict.

##### 6.1.2. Chip Configuration

The current chip configuration has already been used to achieve impressive levels of sensitivity and the discovery of critical biomedical data (e.g., simultaneous identification and analysis of multiple SNP's). However, the current configuration is not sufficient to achieve

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the levels of detection required for the *in vitro* products or the market profile the company seeks. To reach its planned goals, the Company will invest significant time and resources in perfecting the CMOS-based chip design. Toshiba has proven its effectiveness and reliability; however it has experienced identified difficulties in surface preparation of these CMOS chips. Failure to overcome these difficulties could significantly hamper the Company's advancement.

ANTARA has already identified methods to overcome the identified difficulties and expects to perfect the CMOS design within 12 months. However, if unexpected issues arise, progress in this important area could be hindered.

#### **6.1.3. Possible Market Reluctance to Use New Technologies**

The fact that the technology is so innovative and unlike existing technologies, it is possible that there will be certain barriers to entry that are not dependent upon product performance or other common indicators. The Company, however, intends to implement a professionally orchestrated high-profile media campaign to overcome or even preempt such issues. In addition, we will seek strategic partnerships with established entities in order to increase the public awareness and profile of the Company's products and services.

The Company has also assembled a world-class team of researchers in all areas of technology relevant to our products and services, each of which has impressive educational and professional credentials. By executing a well-developed research plan to develop and publicize admirable, yet attainable goals, the Company will take necessary steps toward increasing the public awareness and profile of the Company's products and services.



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## **7. Opportunities**

The opportunities presented by the Company's technology are truly remarkable in both substance and potential market impact. Few, if any, prior products or technologies hold the same promise of sensitivity or compatibility. The Company, through established contacts, intends to aggressively market and launch its products and services in a manner previously unseen in the diagnostics market.

The Company intends to realize its product's full potential through:

- A concerted media campaign
- Capitalizing of the broad range of applicability through strategic licensing arrangements
- Large IPO potential within 12-18 months
- ASR format products
- Homeland security applications (potential for US Government funding and preference)

## **8. Threats/Risks**

### **8.1. General**

#### **Key Personnel**

The Company is highly dependent upon the principle members of our management and research teams. Loss of our key personnel could impede the Company's achievement of R&D, operational or strategic objectives. To be successful, the Company must retain key personnel and attract additional qualified employees.

#### **Infrastructure**

The Company will require significant investment in order to build a manufacture, marketing, distribution and sales infrastructure. The Company intends to benefit from its partners research and clinical laboratory expertise (Eurus, Genesys, CLH, etc.), it will require additional infrastructure which could pose significant challenges to advancement of the intended marketing and revenue-generating strategies.

#### **Legal Expense**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new U.S. Securities and Exchange Commission regulations and NASDAQ Stock Market rules, are creating uncertainty for companies such as ours. To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management

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time and attention from revenue-generating activities. Compliance with changing corporate governance and public disclosure regulations result in additional expenses.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries because of the uncertainties and complex legal, scientific and factual questions related to the ownership and protection of intellectual property. We may be subject to claims that our technology or our products infringe the patents or proprietary rights of third parties. Although the Company has and will continue to take all reasonable precautions to ensure that it does not infringe any patents owned by others, we may be forced to defend against claims of infringement. We may also be required to initiate legal proceedings to protect our patent position or other proprietary rights. These proceedings are often expensive and time-consuming, even if we were to prevail.

### 8.2. Market-Related Issues

Genomics, disease management and polymorphism discovery technologies have undergone and are expected to continue to undergo rapid and significant change. The Company's future success will depend in large part on its ability to maintain a competitive position with respect to these technologies. Rapid technological development by the Company or others may result in products or technologies becoming obsolete. In addition, products offered by the Company would be made obsolete by less expensive or more effective tests based on other technologies or by new therapeutic or prophylactic agents that obviate the need for diagnostic and monitoring information. There can be no assurance that the Company will be able to make the enhancements to its technology necessary to compete successfully with newly emerging technologies.

Competition in genomics, disease management and polymorphism discovery is intense and expected to increase. Further, the technologies for discovering genes and polymorphisms associated with significant diseases and approaches for commercializing those discoveries are new and rapidly evolving.

Currently, the Company's principal competition comes from existing technologies that are used to perform many of the same functions for which the Company plans to market its Genelyzer systems. In the diagnostic field, these technologies are provided by established diagnostic companies such as Affymetrix, Abbott Laboratories, Roche Molecular Diagnostics and Gen-Probe. These technologies include a variety of established assays, such as immunoassays, histochemistry, flow cytometry and culture, and newer DNA probe diagnostics to analyze certain limited amounts of genetic information.

Affymetrix has dominated the gene chip market, aggressively asserting its patents against multiple companies seeking to enter the gene-chip business. While we believe that the Company's technologies are not covered by any Affymetrix patent, it is nonetheless possible that Affymetrix might initiate patent litigation as a means of fending off what will clearly be viewed as a viable threat to its market dominance.

Additionally, in order to compete against existing technologies, the Company will need to demonstrate to potential customers that the Genelyzer system provides improved performance and capabilities. Future competition in these fields will likely come from existing competitors as



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well as other companies seeking to develop new technologies for sequencing and analyzing genetic information. In addition, pharmaceutical and biotechnology companies also are developing or have developed DNA probe based assays or other products and services, some of which may be competitive with those of the Company.

The market for disease management products derived from gene discovery is currently growing but is highly competitive. Many companies are developing and marketing DNA probe tests for genetic and other diseases. Other companies are conducting research on new technologies for diagnostic tests based on advances in genetic information. Established diagnostic companies could provide significant competition to the Company through the development of new products.

These companies have the strategic commitment to diagnostics, the financial and other resources to invest in new technologies, substantial intellectual property portfolios, substantial experience in new product development regulatory expertise, manufacturing capabilities and the distribution channels to deliver products to customers. These companies also have an installed base of instruments in several markets, including clinical and reference laboratories, that are not compatible with the Genelyzer system. In addition, these companies have formed alliances with genomics companies, which provide them access to genetic information that may be incorporated into their diagnostic tests.

### 8.3. Intellectual Property Issues

The Company has taken and will continue to use all reasonable efforts to build a comprehensive patent portfolio and to ensure that it does not infringe the intellectual property rights. Nonetheless, there are issues that may arise.

#### Other Third-Party Patents

Existing intellectual property held by others may not necessarily block any market entry, but it may be difficult to exclude others who already have a significant portion of the intellectual property in the field. A brief review of the intellectual property landscape reveals that Clinical Micro Sensors is probably the single biggest competitor in the field with twenty-one issued US Patents and three published pending applications. These patents and applications generally cover methods of detecting, methods of attaching the probes to the electrodes, the apparatus for use in the detection methods, and compositions for use in the detection methods. Clinical Micro Sensors was acquired by Motorola in 1999 and remains a subsidiary of Motorola Inc. The founders of Clinical Micro Sensors were originally at the California Institute of Technology. A review of the intellectual property in this field held by the California Institute of Technology reveals a similar number of patents and pending applications. A more in-depth analysis of these two portfolios may be warranted, moreover, any licensing deal between the California Institute of Technology and Clinical Micro Sensors may also require investigation and an investment of time and resources.

Other entities having patents and/or patent applications include Bio Merieux, Meso Scale Technologies and Andcare. Significantly, Bio Merieux holds a European Patent, EP 0244,326, which has been characterized as claiming a method of gene detection using a DNA probe fixed to the surface of an electrode and then the variance of the resistance or the

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electrical capacity is measured following hybridization with the test sample. This European Patent to Bio Merieux does not appear to have a related US application or patent. Importantly, however, this European Patent does not appear to cover this embodiment, rather the claims are directed to a method of detecting a biological substance in an electrically conducting medium by comparing the capacitance or resistance of a reference solution, which does not contain the target, and the test liquid which does contain the substance. The presence of the target is denoted by a decrease in this capacitance or change in the resistance, relative to the reference system. Other intellectual property holders in the field are several universities, including University of North Carolina, University of New Mexico, and Harvard University.

Any efforts to secure additional intellectual property rights to protect potential market position will require a more substantive review of the intellectual property held by the entities identified above and others.

#### 8.4. Regulatory Approval

ANTARA faces significant challenges with respect to securing regulatory approval for its products/services. Seeking FDA approval involves significant resources (internal and external) and expense. It is not possible to predict with any degree of certainty the time or expense required in conjunction with securing regulatory approval or if regulatory approval will be received.

ANTARA intends to implement a concerted plan to secure regulatory approval for its diagnostic platform. Through its strategic partnerships and licensing program, ANTARA will proceed with a two-phased plan (ASR → PMA), with the ultimate goal being obtaining FDA approval for its diagnostics platform.

Obtaining FDA approval is a complicated and costly endeavor with substantial rewards. ANTARA has assembled the in-house expertise and experience to bring products based upon its open platform diagnostic system through the maze of regulatory approval. Through its own internal research efforts and in conjunction with its Strategic Partnerships, ANTARA intends to submit the first of several 510(k) pre-market approval applications based upon its electrochemical DNA chip platform within 12-18 months. Current intended targets include products in the pharmacogenomic, infectious disease and cancer prognostic sectors.

The FDA classifies medical devices as class I, II or III according to the level of regulatory control necessary to assure safety and effectiveness. The device classification determines the appropriate regulatory controls. Under current U.S. law, *in vitro* diagnostic products generally fall into two broad categories of classification: and analyte specific reagents (ASRs). In general terms, IVDs include biological products (products made from living organisms used for the prevention, treatment or cure of diseases or injuries) that must meet the requirements of the U.S. Public Health Service. IVDs that are intended for the diagnosis and treatment of human disease are typically classified as class II and in certain instances class III devices. Like other class II and class III medical devices and biological products, IVDs are subject to pre-market approval and post-market controls. In marked contrast, ASRs are defined as "...antibodies...and similar reagents, which through specific binding...with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical

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substance...in biological specimens." The FDA exempts class I ASRs from pre-market submission requirements and considers them to be components of a diagnostic assay.

Classification	General Definition
Class I	Class I devices are subject to the least regulatory control and most are exempt from pre-market notification [510(k)] requirements. They are required only to meet FDA's general controls; that is, they must be manufactured according to Good Manufacturing Practices (GMP) by a registered manufacturer, listed with FDA, and labeled in accordance with the applicable labeling regulations. ASRs are generally as Class I devices. For companies marketing ASRs, the manufacturing facility must be registered and the ASRs must be listed with FDA as medical devices.
Class II	In addition to complying with FDA's general controls, class II devices are required to have 510(k) clearance before being placed on the market and are sometimes subject to special controls such as mandatory performance standards, special labeling or post-market surveillance.
Class III	Class III devices are those that support or sustain life, are important in preventing health impairment or that present a high risk of illness or injury. Class III devices may not be marketed until FDA has approved a pre-market approval application (PMA).

A device submitted using a 510(k) must be compared to a similar product with the same intended use (predicate device) already cleared by FDA. The new device's technological characteristics must be shown through clinical test data to be "substantially equivalent" to the predicate device. For IVD devices FDA also requires comparison to either a reference method (gold standard) or a device having different technological characteristics but the same intended use. For IVDs, the generation of data may be done in-house as opposed to conducting off-site clinical trials. The Company intends to generate data through its own internal research, the research efforts of its Strategic Partnerships and through the application of ASR format products, each of which will be conducted in a manner to facilitate the submissions required for FDA approval. The Company is optimistic that the recent approval of Roche's AmpliChip product (January 2005), will provide sufficient basis to claim that product a predicate device to ANTARA's electrochemical chips, thereby streamlining the approval process.

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#### **8.5. Manufacturing**

The Company has several viable options, which it is considering with respect to the manufacture of the instruments and chips.

##### **8.5.1. Instruments**

The Genelyzer™ instruments have, to date, been manufactured by Toshiba. The present estimated manufacturing cost of the instruments is \$15-20K.

The company intends to pursue domestic production through either (or both) capital investment in a production facility in a West Coast state (e.g., California, Arizona, Nevada, Washington) or through an outsourcing agreement with existing instrument manufacturer or by capital investment in a production facility. The initial financial requirement for the capital investment model is estimated at \$10-20M.

The Company is currently evaluating several opportunities with existing instrument manufacturers. Due to adverse market conditions in certain segments of the scientific instrument business (e.g., Multiplex QPCR thermocyclers), there are companies with proven quality and performance records that have existing manufacturing capacity. Certain of these candidates have experience in the production of molecular diagnostic devices, which have been utilized for FDA approved applications and which are FDA registered facilities.

##### **8.5.2. DNA Chips**

The Genelyzer™ instruments have, to date, been manufactured by Toshiba. The chips will initially be manufactured by Toshiba. Toshiba presently estimates its production capability at approximately one million chips/year.

The Company is currently negotiating the terms of an agreement under which Toshiba will supply ANTARA with its requirement of chips. The cost to ANTARA has yet to be determined.

The Company is currently evaluating additional manufacturing options with respect to the manufacture of DNA chips.

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## 8.6. Revenue/Expense: Comparative Business Models

	GLOBAL (\$)			2004 REVENUES	
	2004	2003		(in millions)	
IVD MARKET (in millions)	28,877.7	43,189.0		IMMUNO-CHEMISTRY	\$6,958.8
COMPOUNDED ANNUAL GROWTH RATE		7.1%		CLINICAL CHEMISTRY	\$6,710.6
				SMEO	\$5,867.9
MOLECULAR DIAGNOSTICS (in millions)	1,587.2	3,680.7		HEMATOLOGY	\$1,877.3
COMPOUNDED ANNUAL GROWTH RATE		15.3%		MICROBIOLOGY	\$1,848.0
				MOLEC. DIAGNOSTICS	\$4,561.2
				POC	\$4,561.9
				HEMOTASIS	\$4,136.7
				URINE	\$535.3
				DIABETES	\$448.2
				OTHER	\$535.2
				TOTAL	\$28,877.7

	U.S. (\$)	
	2004	2003
IVD MARKET (in millions)	11,538.2	17,318.2
COMPOUNDED ANNUAL GROWTH RATE		6.4%
MOLECULAR DIAGNOSTICS (in millions)	1,763.0	2,865.3
COMPOUNDED ANNUAL GROWTH RATE		19.7%

AFFYMETRIX				
	2001	2002	2003	2004
PROBE ARRAYS SALES		140,839,000	139,591,000	188,243,000
REAGENT SALES		15,341,000	20,419,000	31,754,000
TOTAL TEST SALES	101,518,000	155,380,000	160,010,000	198,987,000
INSTRUMENT SALES	46,948,000	48,214,000	62,776,000	77,269,000
OVERALL GPM %	59.9%	59.0%	82.0%	70.5%

PCR Instrument/Reagent Company Model				
	2001	2002	2003	2004
TOTAL TEST SALES	11,698,750	31,314,000	52,277,250	69,696,750
INSTRUMENT SALES	14,888,750	16,129,000	17,425,750	21,203,250
TEST GPM %				75.0%
INSTRUMENT GPM %				50.0%
OVERALL GPM %	65.5%	65.0%	48.6%	65.4%

IVD Company Model					
	2001	2002	2003	2004	2005
TOTAL TEST SALES	18,392,549	32,624,900	51,113,000	74,581,000	91,487,000
INSTRUMENT SALES	4,062,098	4,062,000	2,371,000	6,432,000	6,565,000
OVERALL GPM %	63.9%	73.0%	79.0%	81.9%	82.0%

INSTRUMENT PRICING	AFFYMETRIX	OPCR	IVD
	typically leased	\$25,000 - 60,000	typically leased
MANUFACTURING FACILITY			
TOTAL SQUARE FOOTAGE	52,000	85,000	11,000 (45% manufacturing)
OWN/LEASE	OWN	OWN	LEASE
YEAR BUILT	1989	1999	1999
PRODUCTS	TEST	TEST/INSTRUMENT	TEST/INSTRUMENT
INITIAL INVESTMENT	\$5-16 million + Land	\$11.4 million	
CURRENT ANNUAL FACILITY/OVERHEAD COSTS		\$7.9 million	\$9.9 million
TOTAL SQUARE FOOTAGE	80,000		
OWN/LEASE	LEASE		
YEAR BUILT	2000		
PRODUCTS	INSTRUMENT/R&D		
INITIAL INVESTMENT			
CURRENT ANNUAL FACILITY/OVERHEAD COSTS			

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## 8.7. Five Year Projections

Antara  
PROJECTED FIVE YEAR EXPENSES

## Expense Projections

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Description	Cost	Cost	Cost	Cost	Cost
FDA Approval Process	\$ 10,000,000.00	\$ 10,000,000.00	\$ 30,000,000.00	\$ 30,000,000.00	\$ 25,000,000.00
Operating Cost					
Infrastructure					
equipment	\$ 2,000,000.00	\$ -	\$ -	\$ -	\$ -
office remodel, furnish, school	\$ 1,500,000.00	\$ -	\$ -	\$ -	\$ -
factor	\$ -	\$ 8,000,000.00	\$ 18,000,000.00	\$ -	\$ -
facility lease	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00	\$ 1,500,000.00
Research and Development	\$ 15,000,000.00	\$ 20,000,000.00	\$ 25,000,000.00	\$ 25,000,000.00	\$ 25,000,000.00
Intellectual Property					
Patent Prosecution/Obtain	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00
In-Licensing	\$ 2,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00
Litigation Reserves	\$ -	\$ 5,000,000.00	\$ 10,000,000.00	\$ 10,000,000.00	\$ 10,000,000.00
Marketing and Advertising	\$ 2,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00	\$ 10,000,000.00
Salaries	\$ 7,000,000.00	\$ 8,000,000.00	\$ 10,000,000.00	\$ 11,000,000.00	\$ 15,000,000.00
General Administrative	\$ 2,000,000.00	\$ 2,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00
Information Technology (IT)	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00
Legal	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00	\$ 2,000,000.00
Regulatory	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00	\$ 1,000,000.00
Consultants	\$ 4,000,000.00	\$ 4,000,000.00	\$ 4,000,000.00	\$ 5,000,000.00	\$ 5,000,000.00

TOTALS \$ 74,000,000.00 \$ 91,000,000.00 \$ 144,000,000.00 \$ 132,500,000.00 \$ 141,500,000.00

TOSHIBA Initial Payment  
Clinical Laboratory for ASIR

JPY 1,000,000,000  
\$ 19,000,000.00 \$ 15,000,000.00 \$ 25,000,000.00 \$ 30,000,000.00 \$ 35,000,000.00

TOTALS \$ 74,000,000.00 \$ 91,000,000.00 \$ 144,000,000.00 \$ 132,500,000.00 \$ 141,500,000.00

Revenue Projections:					
Markers (Hepatitis, HIV, Dengue, etc.)	\$ -	\$ 30,000,000.00	\$ 50,000,000.00	\$ 100,000,000.00	\$ 150,000,000.00
Infectious Disease	\$ 20,000,000.00	\$ 50,000,000.00	\$ 100,000,000.00	\$ 250,000,000.00	\$ 250,000,000.00
- bird flu detection					
- mad cow detection					
Home Land Security	\$ 00,000,000.00	\$ 75,000,000.00	\$ 75,000,000.00	\$ 100,000,000.00	\$ 100,000,000.00
- Anthrax					
TOTALS	\$ -	\$ 70,000,000.00	\$ 155,000,000.00	\$ 235,000,000.00	\$ 500,000,000.00

Profit \$ (74,000,000.00) \$ (21,000,000.00) \$ 11,000,000.00 \$ 102,500,000.00 \$ 358,500,000.00

New Fund Money \$ 75,000,000.00 \$ 25,000,000.00 \$ - \$ - \$ -

Financial Balance \$ 1,000,000.00 \$ 5,000,000.00 \$ 16,000,000.00 \$ 118,500,000.00 \$ 477,000,000.00

Human Resource					
MANAGER	15	20	25	25	30
staff and assistants	30	50	75	100	120



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## 9. ANTARA POSSIBLE EXIT STRATEGIES

ANTARA's founded capitalization is valued at \$100,000,000 (\$1,000,000 per percentage ownership). Based upon current market valuations, value a company having ANTARA's technology, management team and scientific staff and leadership at approximately \$350,000,000. Thus, the initial investors will hold a 3.5:1 advantage. The Company presently intends to execute the planned milestone timetable and position itself for an initial public offering ("IPO") in December 2006. Preliminary discussions with Wallstreet market-makers indicate that the timing for such an offering in the U.S. biotech sector could be optimum, with an expected IPO value on the order of US\$750 million. These estimates are based upon several factors including:

- (a) anticipated market demand for biotech stocks (based upon current and expected demand by institutional investors;
- (b) an increased demand for and recognition of *in vitro* diagnostic products and novel platforms;
- (c) market capitalization ("market caps") of companies, which are similarly, situated despite inferior technologies and/or IP positions.

Representative market cap comparisons include the following companies:

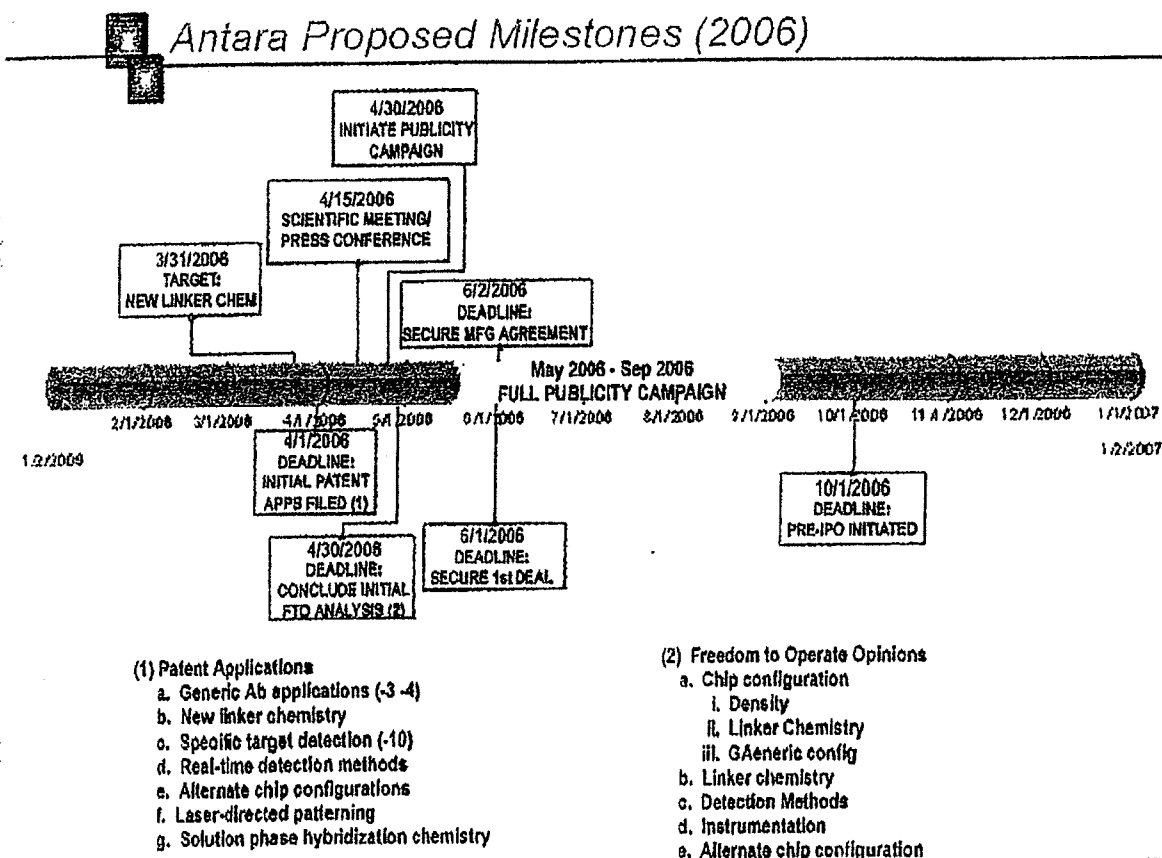
<u>Company</u>	<u>November 2005 Market Cap</u>
Affymetrix	\$3,308,137,000
Invitrogen	\$3,405,776,000
Gen-Probe	\$2,314,000,000
Ventana Medical Systems	\$1,445,475,000

Initial investors will have the opportunity to sell shares during the IPO should they desire a short-term return on investment.

Should the Company decide that an IPO is not the optimal vehicle for the return on investment, other options include an asset sale which is presently estimated to provide the potential for a short term exit strategy with an expected return on investment estimated at 3-5 times initial investment values.

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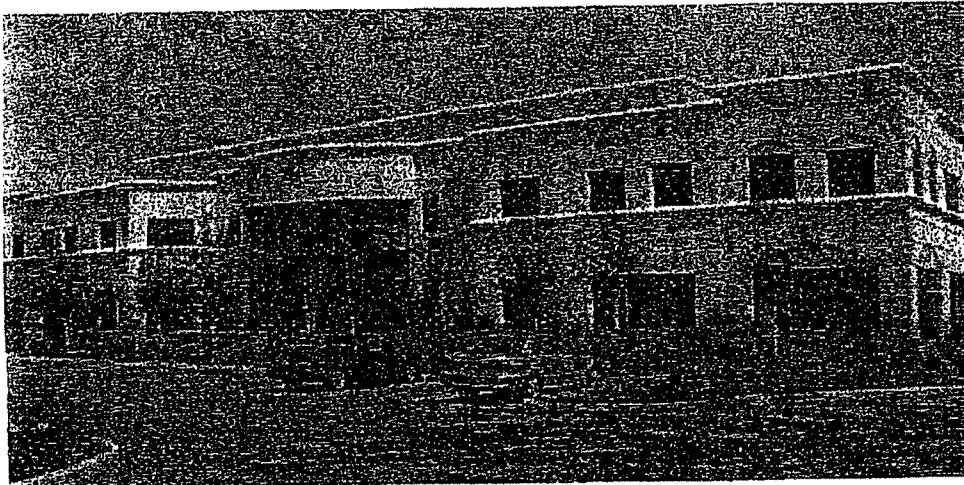
## 10. Proposed Milestones



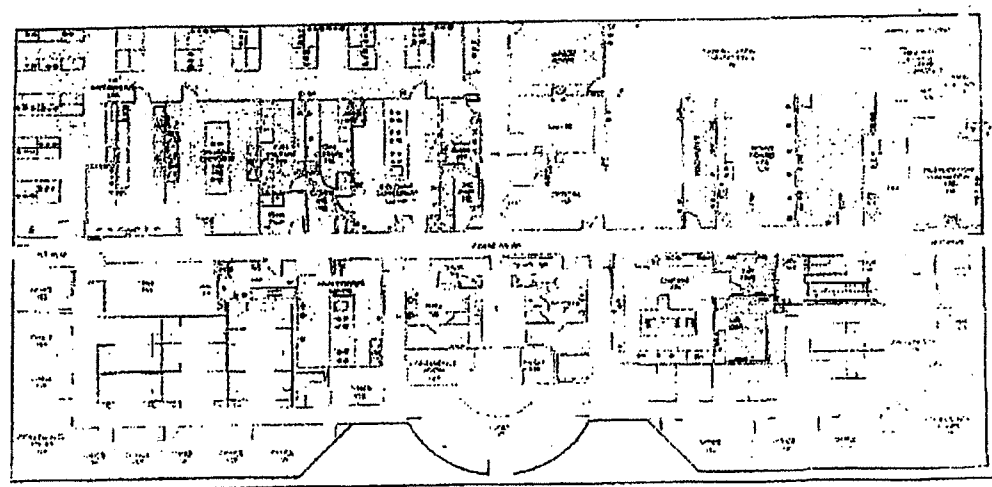
## 11. Proposed Site

A state-of-the-art facility located in Mountain View, California has been selected as the proposed main site for further research, development, and corporate offices. This space is located in the heart of the Silicon Valley, just 15 minutes from Stanford University and within a half hour of two international airports (San Francisco and San Jose). Other companies located in the immediate neighborhood proximity include Perlegen, Google, Intuit and Alza Pharmaceuticals.

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The facility includes over 44,000 square feet (4,420 square meters) of plug and play laboratory and office space. The following layout represents the first floor of this two-story building. The blue-shaded areas are laboratory space. The orange-shaded areas are "clean room" space for chip manufacture.

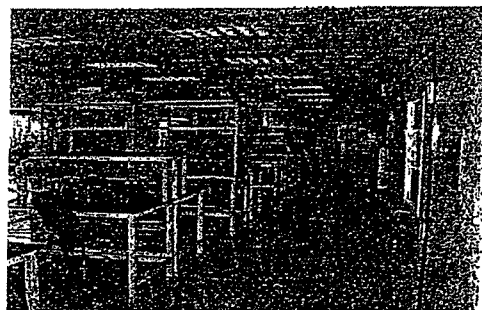
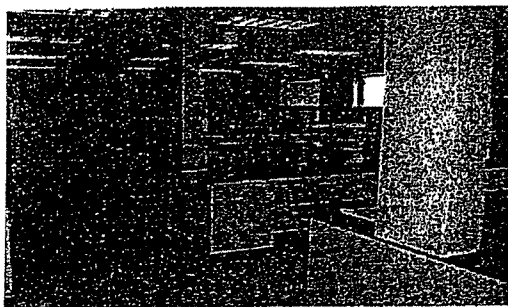
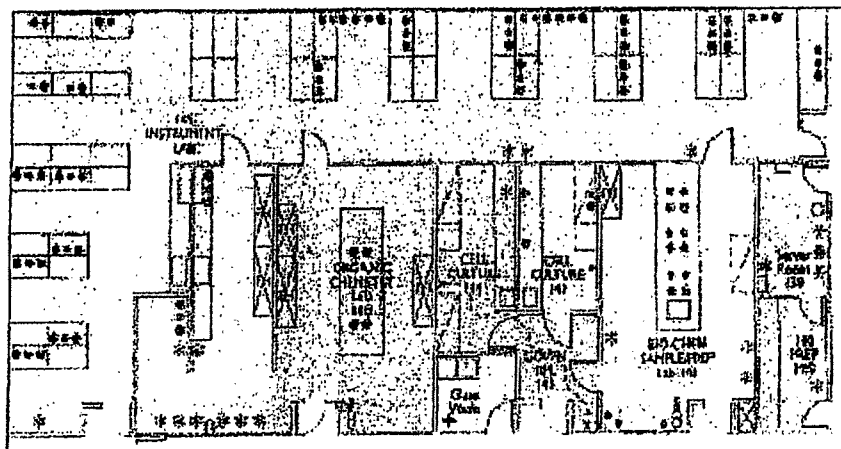


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There are several key areas, which are highlighted below. The first is the molecular biology wet lab. The enlarged floor plan (shown in blue below) and additional photos below provide a clearer view of this space.

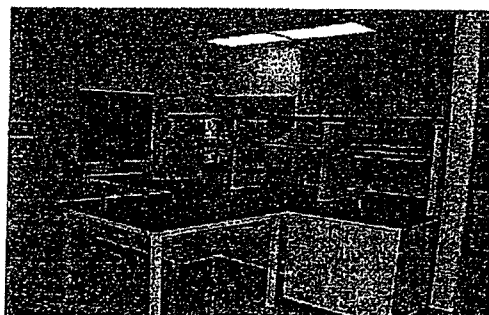
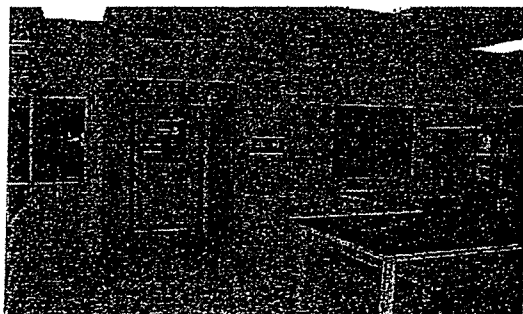
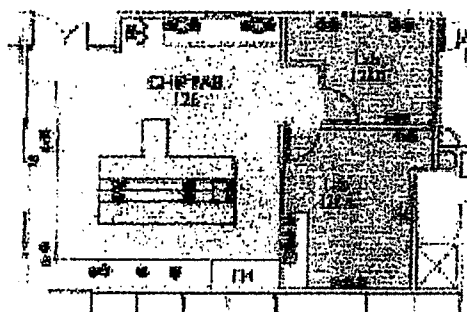


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The chip fabrication lab and clean rooms are another key area and are displayed below.

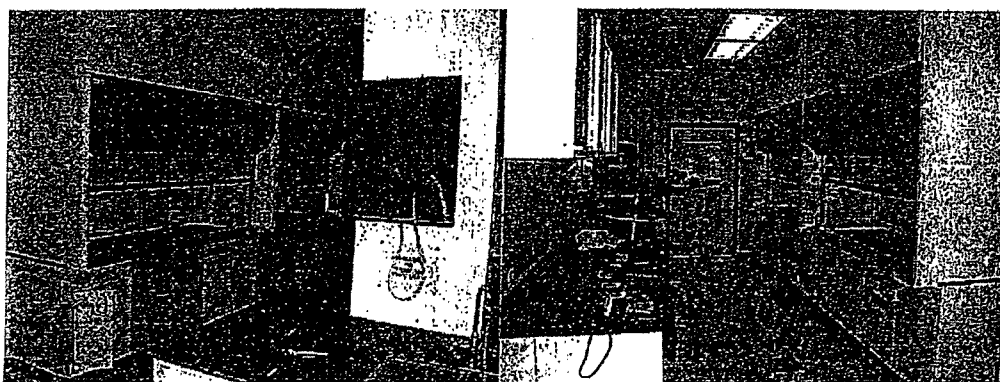
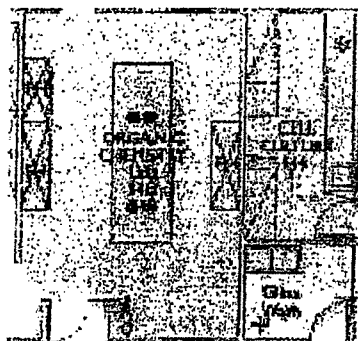
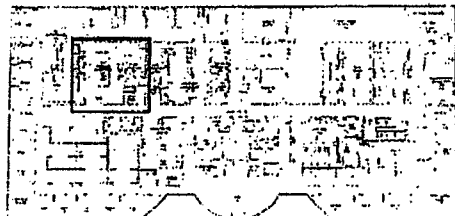


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Organic chemistry (in addition to cell culture laboratory space) provides the lab functionality required for surface chemistry optimization.



The Mountain View facility is ideal for ANTARA's present plans and will afford additional space required for the Company's growth and expansion.